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In the Supreme Court of the United States

OCTOBER TERM 1957

MARION B. FOLSOM, Secretary of Health, Education and Welfare,
Petitioner,
-vs-
FLORIDA CITRUS EXCHANGE, et al,
and
FRANK R. SCHELL,
Respondents.

No. 27

BRIEF OF RESPONDENT FRANK R. SCHELL IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI.

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-vs-	)	
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	)	October Term 1957
and	)	
FRANK R. SCHELL,	)	
Respondents.	)	

Brief of Respondent Frank R. Schell in Opposition to Petition for Writ of Certiorari

Preliminary Statement

The respondent, Frank R. Schell, respectfully presents this brief in opposition to the petition of Marion B. Folsom, Secretary of Health, Education and Welfare, for writ of certiorari.

In this brief the following abbreviations and designations will be used:

"Secretary" refers to Hon. Marion B. Folsom, Secretary of Department of Health, Education and Welfare;

"Respondent" refers to Frank R. Schell;

"PB—" refers to pages of Secretary's petition and brief;

"R——" refers to pages in Record before C.C.A., Fifth Circuit;

"JA—" refers to pages in Joint Appendix before C.C.A., Fifth Circuit;

"A" refers to page number of Appendix in this Brief;

"USDA" refers to U. S. Dep't of Agriculture;

"F&DA" refers to U. S. Food and Drug Administration;

"The Act" refers to Federal Food, Drug and Cosmetic Act;

"Color Added" refers to a process for coloring oranges with a coal-tar color;

"Red 32", or similar words, refers to FD&C Red No. 32 and other coal-tar colors.

"Dunn, p.——," refers to pages in Charles Wesley Dunn's work "Federal Food, Drug and Cosmetic Act" (1938), compilation of the official records of the Congress, which we make use of in this brief in discussing the legislative history of the Act.

"p.p.m." refers to "parts of color per million parts of food so colored."

Errata in "Record"

At p. 244, line 12, the figures "710/0" should read "7/100".

At p. 247, line 8, par. numbered "2"; 5th word "do" should be "so".

At p. 251, the third complete paragraph reads:

> 'On January 19, he said, the administration would open formal hearings **on the subject of whether orange color with coal-tar dyes."**

Whereas the same should read:

> "On January 19, he said, the administration would open formal hearings **on the subject of whether orange growers would be allowed to continue tinting their fruits orange color with coal-tar colors."** See correct quotation, par. 2, p. 252.)

Opinions Below

The Secretary's order (R 281) appears in 20 F. R. 8493. The opinions of the Court of Appeals, Fifth Cir-

cuit, are reported in 246 Fed. 2nd 850 and appears PB 25-52. The opinion of the Court of Appeals, Second Circuit, is reported in 236 Fed. 2nd 866 and appears in the appendix to this brief at pages A-1 to A-7.

Jurisdiction

The Secretary seeks to invoke the jurisdiction of this Court on the ground that the decision of the Circuit Court, Second Circuit, and the decision of the Circuit Court, Fifth Circuit, are in basic conflict. It will be the contention of respondent that no basic conflict exists and that the decisions of the two courts are basically in harmony as to the law.

Statutes Involved

The Federal Food, Drug and Cosmetic Act, as amended, 52 Stat. 1040, 70 Stat. 512 (21 U.S.C. 301, et seq.) provides in all of its pertinent parts as follows:

"Sec. 402. A food shall be deemed to be adulterated—

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance, **except a pesticide chemical in or on a raw agriculture commodity**, which is unsafe within the meaning of section 406, **or if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of Section 408 (a)**; or • • •

"(c) If it bears or contains a coal-tar color other than one from a batch that has been certified

in accordance with regulations as provided by section 406; **Provided that this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this act for the purpose of coloring citrus fruit:** Provided further, That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as 'packing house elimination') the skins of which have been colored at any time prior to March 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as FD&C Red 32, or certified after such enactment as External D&C Red 14 in accordance with section 21, Code of Federal Regulations, part 9: And provided further, That the preceding proviso shall have no further effect if prior to March 1, 1959, another coal-tar color suitable for coloring oranges is listed under section 406." (21 U.S.C. 342)

• • • •

"Sec. 406 (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding

the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any such added amount of such substance, be considered to be adulterated within the meaning of clause 1 of section 402 (a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents" (21 U.S.C. 346).

• • • •

"Sec. 701 (f) (1). In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order***"

• • • •

"(3) The court shall have jurisdiction to affirm the order, or to set it aside in whole or in

part, temporarily or permanently. * * * The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

"(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari * * *" (21 U.S.C. 371).

(Emphasis supplied indicates portions omitted from Secretary's quotation of the Act "in pertinent part." PB 3-5).

Questions Presented

We respectfully submit to this Court that the questions submitted by petitioner do not, in our opinion, correctly set forth the issues before this Court and we submit as questions presented, the following:

(1) Whether there is any basic conflict between the decision of the Circuit Court of the Second Circuit and the decision of the Circuit Court of the Fifth Circuit.

(2) Whether the Circuit Court, Fifth Circuit, erred in holding that Red 32 is "harmless and suitable for use in foods," for coloring of oranges only, within the contemplation of the Food, Drug and Cosmetic Act.

(3) Whether the Circuit Court, Fifth Circuit, erred in holding that the Secretary had the authority under the Federal Food, Drug and Cosmetic Act to fix tolerances for use of coal-tar colors on or in specified foods.

(4) Whether the Circuit Court, Fifth Circuit, erred in holding that the Secretary had authority under the Federal Food, Drug and Cosmetic Act to limit the use of Red 32 to use in coloring oranges.

Statement Of The Case

The Color Added process was perfected in 1933, (R. 217) but due to an improper ruling by Mr. Walter G. Campbell, then Chief of F&DA, that the process could not be used at all (R. 221) did not go into commercial use until the Fall of 1934, after a ruling by the Solicitor for U.S.D.A., dated February 28, 1934, settled the points of law concerned, overruling Mr. Campbell's total prohibition of use, but requiring the labeling "Color Added" (from which the process derived its name) on the peel of each orange. (R. 222).

The history of Color Added is recited at R. 214-227. We respectfully request and urge that the Court carefully consider that record of:

(1) The early attempted total prohibition of use by the Chief of F&DA, alleging the use of color to deceive the consumer, which charge was completely refuted and overruled during the series of hearings during 1934, 1935, 1936, and 1937, all designed to induce the Secretary of U.S.D.A. to uphold that total prohibition of use (R. 220-223);

(2) The attempts of F&DA to procure legislation that would enable it to out-law the Color Added process by withholding certification of food colors indispensable to the operation thereof and the defeat of all such attempts (R. 224-227);

(3) The final agreement of Mr. Campbell and Hon. J. Hardin Peterson, then Representative from the First Congressional District of Florida and now Counsel in the instant case, relating to terms of the Act (R. 227) and

(4) The subsequent drafting of amendments to the pending legislation (which amendments were finally incorporated in Sec. 402 (c) and

Secs. 406 (a) and 406 (b) of the 1938 Food, Drug and Cosmetic Act as enacted) (R. 228) each of said amendments (as then concurred in by the then Chief of F&DA) having the specific purpose of preventing F&DA destroying the Color Added process by denying certification to colors indispensable to the operation thereof.

There was no further interference with Color Added by F&DA until 1953. From 1937, until now, there has never been a complaint to (or by) F&DA that the process was being improperly operated or improperly used or that the States of Florida and Texas were not properly policing the use of the process. Nor has there been so much as a suggestion that the health of any person has ever been adversely affected by eating Color Added oranges.

As will hereinafter be shown (p. 28-29) the word "harmless", in regulations re food colors, had been used and construed in its **relative** sense from the first regulations issued in 1907. Congress used the word in that sense in, and this interpretation and construction continued under, the 1938 FD&C Act. Thus, at the very first hearings re-certification of food colors under the 1938 Act, held in 1939, the word "harmless" was very clearly construed, by the then head of the Division of Pharmacology of F&DA, as being used in a relative sense, i.e., harmless in the amounts of ordinary usage (R. 170, 177-178) and Red 32 was certified and Orange 2, previously certified under the name Orange SS, was recertified. In 1940, following those hearings, F&DA issued its "Coal Tar Color Regulations" (SRA, FDC 3) pursuant to provisions of 1938 Food, Drug and Cosmetic Act, which Regulations carried that interpretation into effect, and established tolerances for coal-tar colors, as hereinafter shown (p. 45-46).

Thereafter, until the spring of 1953 — 15 years —

such certification continued without any question of the entire harmlessness of that color.

Moreover, on Oct. 13, 1952, the Associate Commissioner of U.S. F&DA addressed a letter to Mr. Randall Chase, of Sanford, Florida, which began (R. p. 72):

> "Let me say at the outset that this Administration is in agreement with your conclusion that the use of added color is inherently deceptive and is contrary to the interests of both consumers and producers."

The above quotation appears in a brief filed in the Department proceedings (R. p. 72). In the next sentence, discussing additional statements made in the Associate Commissioner's letter to Mr. Chase, but not quoted, the Brief continues:

> "We are in entire accord with that administrative position. We are in disagreement, however, with **the view apparently taken at that time that the legislative history of the Act requires a conclusion that the law does not ban the use on oranges of such dyes** as create an economic cheat upon the consumer".

Thus, as late as October, 1952, we find F&DA adhering to that construction of the word "harmless" in its **relative** sense, as being the intent of the Congress.

Of course, if the color created "an economic cheat" it was the use, not the color, that would be subject to attack. If the color was "harmless" according to the intent of Congress, the color was eligible for certification although the use made thereof might be subject to criticism — but no such criticism has been or could be raised by F&DA in these proceedings, for that charge had been completely refuted back in 1933-37.

Then, in about March of 1953, the manufacturers of Red 32 were informed that F&DA was re-examining the whole question of possible toxicity of all certified

coal-tar food colors, but such advices were accompanied by assurances that F&DA understood and appreciated the importance of the Color Added process to the citrus industry of Florida and Texas, and that such re-examination was in no wise hostile thereto (R 250-251).

F&DA then initiated a series of abbreviated tests of Red No. 32, which ran for 173 days only, and, on the strength of these abbreviated tests, F&DA then repudiated the results had from a series of tests over a period of six years (1938-1944) (JA 85-86) and, in about November of 1953, informed the color manufacturers that F&DA proposed to delete Red 32, Orange 2 and Orange 1 from the list of certifiable dyes, which, of course, would prohibit use of the Color Added process, since only certified food colors may be used in or on foods. F&DA protested their regret at being forced to take such action, but asserted their lack of alternative in view of their Counsel's construing the word "harmless" in the Statute as requiring "zero toxicity". (R. 256-257).

On January 1st, 1954, **Commissioner George R. Larrick,** in an interview with a Washington newspaperman, **identified the purpose of the hearing** to be held on January 19, 1954, as being the determination of **"whether orange growers would be permitted to continued tinting their fruits orange color with coal-tar dyes." (R 251).**

When this Respondent learned, on December 18, 1953, of the real purpose of the hearings, and especially after the confirmation by Commissioner Larrick on January 1st, 1954, it was then far too late to employ Counsel and inform them as to the ramifications of a highly technical subject matter and be properly represented at the hearing on January 19, 1954, and this Respondent necessarily was not represented (R. 210-211). Also, feeding tests at proper levels, having some relation to public health, and analyses to determine the color content of all

foods colored with the three colors, would have required a minimum of one year's time. Some data was presented by Counsel for the color manufacturers, from the Florida Citrus Commission, as to amount of added color deposited in the peel of Color Added oranges (4 parts of color per million parts of whole orange); in the juice, (7/100 of 1 ppm); and in candied orange peel (7.4 ppm) and marmalade (1.8 ppm) when made from Color Added oranges (JA. 45). No other presentations by Respondent or the citrus industry were possible, for reasons stated.

At the hearing on January 19, 1954, while admitting (JA 25 - 26) that they had no information as to harmfulness of the colors at "levels of ordinary normal conditions of use", F&DA presented data which proved only that test animals can be made ill by the colors when fed amounts thereof which are vastly in excess of normal uses in foods, a result that would, of course, follow from like excessive consumption of any other substance possible of being ingested by man. (JA. 6-39; Exhibits JA. 49-93).

On February 7, 1955, Mr. George P. Larrick, Commissioner of Food and Drug Administration, addressed a letter to Florida's Senator George A. Smathers, reading, in pertinent part, as follows (R. 236):

> "The proposal to remove these coal-tar colors, including FD&C Red No. 32, from the list of colors eligible for certification for use in food results from the requirements of the Pure Food Law that only colors that are harmless are eligible for certification. Recent investigations show that these colors, when fed in substantial amounts, show evidences of toxicity. **There is, however, no evidence that, in the amounts used, and in the manner of use, in the coloring of citrus fruits, the product so colored is not safe for human consumption.". (Emphasis supplied).**

In his statement, on February 10, 1956 ("Hearing before a Sub-Committee on Interstate and Foreign Commerce, H.R., 84th Congress, 2d. Session, on H.R. 7732") (which became P.L. 672) Mr. Larrick said (p. 18):

> "Considering all of the information so far available — and bearing in mind particularly **the minute amount** of the dye likely to enter the human diet as a result of its use on oranges — we cannot say that its continued use on oranges, not intended for processing, would pose a hazard to the public health." (Emphasis supplied).

This Respondent, on March 5, 1955 presented his petition to intervene, in his own name, along with Exceptions and Brief and petition to reopen taking of testimony (R. 209-251) **all within the required time for pleading to the proposed Order.** The Exceptions, Brief and Petition presented matters and things that were self-evidently important and necessary to any proper consideration of the Proposed Rule Making (R. 209-213).

Respondent's pleadings were admitted to the record but his petition to reopen the proceedings, so as to give Respondent and the Florida citrus industry their day in Court, was ignored.

On November 10, 1955, the Secretary issued the final Order appealed from and there followed the proceedings in Fifth Circuit Court of Appeals and the decision of July 12, 1957, which held (Chief Judge Hutcheson dissenting) (1) that the word "harmless" should be construed in accordance with the rule laid down by the Supreme Court in **U.S. vs. Lexington Mill & Elevator Co.** (232 U.S. 399); (2) that the Secretary has the power to fix maximum limits of use (tolerances) for coal-tar food colors and (3) that the Secretary has and has exercised the power to limit the use of a specific color to one specific usage, and ordered the Secretary to proceed accordingly.

F&DA filed their petition for rehearing, which was denied by memorandum decision, Per Curiam, on August 28, 1957, Chief Judge Hutcheson again dissenting.

The mandate issued on October 12th and F&DA are now prosecuting their Petition to this Court.

Before proceeding to our argument we find it necessary to first correct certain

Errors in Petition for Certiorari.

At lines 5-8, Second paragraph, p. 13 of Petition, referring to the decision of Fifth Circuit Court, it is said:

> "It effectively defeats the object of Congress — in passing P.L. 672, the temporary legislation — of stimulating the color industry to develop new and safer coloring."

This is directly contrary to the statement in Committee Report on H.R. 7732, which became P.L. 672 (Senate Report 2391, June 29, 1956, 84th Congress, 2d Session) which reads:

> "Inasmuch as the judicial proceedings referred to above have not as yet been concluded, **the committee wants to make it clear** that if it is finally judicially determined that the Secretary of the Department of Health, Education and Welfare already has the power to certify FD&C Red No. 32 for use on the exterior of oranges, **the instant legislation is not intended to limit or modify that power.**" (Emphasis ours).

Again, the petition, beginning at "B", p. 15, through first complete par. on p. 16, urges this Honorable Court to grant its writ of certiorari because:

> "* * * Congress intended by P.L. 672 to press the color industry and the orange growers into prompt development of a harmless color or at least into scientific research which might pro-

vide a sound factual basis for a safe tolerance for Red 32 on oranges. * * *

"The decision below means, however, that the industry and the growers can rest on the Fifth Circuit judgement and do nothing * * * There is now no need for the industry to institute studies or to take action. **On the other hand, the scientific evidence to support the course of action required of the Secretary by the Court below does not now exist, and the investigations to obtain it will involve considerable expense and require at least two years after the study is commenced.** If the Secretary really does have the burden which the decision below c a s t s upon him, he should know that now. If, as we think, the burden is properly on the industry, the decision below, under which the industry need do nothing, should not be allowed to stand."

Thus it is sought to show to this Honorable Court that the Secretary fears, and has reason to fear, that, by reason of the Fifth Circuit's decision:

The color industry and the citrus industry ("citrus industry" includes proponents of the Color Added process) will be released from the compulsion the Congress intended to put upon them to undertake:

(a) Prompt development of a harmless color for oranges, or, at least,

(b) Scientific research which might provide "a sound factual basis for a safe tolerance for Red 32 on oranges;" and

(c) That, accordingly, the color industry and citrus industry will do nothing to those ends unless that decision be reversed; and

(d) An improper burden of work and expense, for (b), above, will thereby be imposed upon the Secretary.

We first respectfully submit that the Secretary did not, as asserted at "5", pp. 10-11 of Petition, win approval from the Congress as to his opposition to the Bill introduced as H.R. 7732. The fact is that Commissioner Larrick conferred with Hon. J. Hardin Peterson, Counsel for the citrus industry, before the Committee meeting, to talk compromise, Mr. Larrick's principal desire being to limit continued use of Red 32 to a perod of three years, which the industry readily accepted, since it afforded ample time to complete the research program that had then been under way since about May of 1954, and ample time in which to conclude this litigation.

The Committees of the House and Senate, therefore, did not decide any contest in the Secretary's favor, because there was no contest to be decided, but, instead, approved a non-controversial amendment which had the blessing of both the industry and F&DA. The Secretary's letter, stating his position, was dated February 13, being three days after the Committee hearing.

We respectfully request that the Court note these statements, made by Hon. J. Hardin Peterson, representing the Florida and Texas citrus industry, to the House Committee (Mr. Larrick being present) (Hearing, Supra, p. 15 at pp. 7-9 of transcript.)

> "Since I came here, Dr. Larrick of the Food and Drug Administration has shown me a statement which he is going to make. That statement will help us in our problem.
>
> • • • •
>
> "•• I will not get into the presentation, but with your permission I will put my statement in the record, because Dr. Larrick has told me

that he is willing to continue the certification of this color for 3 years. The formal report is being prepared, and he has a statement which he is going to give to the committee this morning. That will give us the time to come up with research and it will not throw the industry in a turmoil.

"Mr. Dies, 'That will eliminate the necessity for legislation?

"Mr. Peterson. No, sir, we will need legislation, but they are going to agree to it. They are going to agree to the legislation, limited to 3 years instead of indefinitely. With that, I think that we will be able to get this without trouble. We are in accord on that.

• • • •

"Mr. Peterson. Now, that is roughly the situation. **• • • I do not think I ought to argue the case if it looks like I have won it".**

Mr. Larrick thereafter stated to the Committee (p. 17):

"I am particularly glad, on my first appearance before this committee, since I became Commissioner, that it apparently will be a non-controversial hearing."

It is likewise respectfully submitted that the Congress had no intent, or occasion for intent, to press the color industry or the citrus industry to do anything whatever, the Congress being fully informed and advised, at the above mentioned Hearing had on H. R. 7732 (which became P.L. 672) that such work was then already well under way, and that no expenditure of time or money therefor, by the Secretary, was contemplated.

At line 13, p. 19 of the transcript of that "Hearing", we find this statement by the Chairman:

"I understand that under the terms proposed, there would be an amendment to the bill limit-

ing it to a 3 year period, during which time **growers and users of this color will make tests and conduct examinations and experiments** to determine whether **a substitute color** can be used." (Emphasis ours).

The Court is requested to note, further, this quotation from Committee Reports (H.R. Report No. 1982, Senate Report No. 2391, 84th Congress, 2d. Session):

> "However, the Committee concluded that this legislation should be limited to a maximum period of 3 years. This will allow time for the necessary scientific studies in the development of a harmless synthetic color. **The Committee received testimony that these studies are well under way and promise to yield good results.** The bill, as amended, will also allow time for a further exploration of the toxicity of FD&C Red 32. Before a final conclusion about the precise toxicity of this color can be drawn, it is necessary to conduct comprehensive scientific studies of chronic toxicity with laboratory animals over their life span. **This will involve feeding tests at levels relating to the quantities of the color that might enter man's diet from his consumption of colored oranges.** Such tests and studies will require approximately 3 years and **the industry is expected to make these studies during this period.**"

We will now discuss the above allegations of the Secretary's Petition under the listed headings:

The alleged intent of the Congress to press the industry to undertake: (a) Prompt development of a harmless color for oranges.

The Solicitor General; and Mr. William W. Goodrich, Assistant General Counsel, Department of Health, Education and Welfare; and Mr. George P. Larrick, Com-

missioner of Federal Food and Drug Administration, have, through Senator Spessard L. Holland, of Florida, authorized us to say to this Court that they have no objection to the recital of certain matters and things, from outside the record, re the industry's program for research as to a new color, in response to this allegation. We now inform the Court of the facts relative thereto:

The officials of F&DA have been kept fully informed and advised, at all times since the early months of 1954, that the citrus industry was then instituting, and has ever since been vigorously prosecuting, a complete program of research as to the toxicity of a new color, now known as Citrus Red No. 2, to replace Red 32 (and Orange 2, so far as coloring oranges is concerned); that this research has gone forward unceasingly and had been completed some months before the Secretary's Petition was written; that application for certification is now being prepared. (That application will likely have been filed with F&DA before this Brief is filed with this Honorable Court.)

F&DA were consulted, in early 1954, as to levels of feedings to be followed, i.e., ratio of color to food. The officers of Pharmacological Division of F&DA suggested and advised that such research include feeding trials at 1.0 per cent, 3.0 per cent and 5 per cent (10,000, 30,000 and 50,000 parts of color per million parts of food). The industry acceded, although well knowing (as does F&DA) that it is impossible, to this time, to formulate a coal-tar color having "no effect" when fed at ratios of 30,000 to 50,000 p.p.m. When the adverse results to be anticipated from feeding at those fantastic levels were had, the tests at those levels were discontinued.

Feeding tests were continued at lower levels and, when completed, the results showed a "no effect level"

at 1,000 p.p.m., being at least 250 times and, quite possibly, 500 times the amount of color that will be deposited in the peel of an orange colored therewith, as Citrus Red No. 2 has a much greater tinctorial power than Red 32, of which only 4 p.p.m is found in the peel of the orange.

While these feeding trials were under way, the officials of F&DA suggested metabolism and excretion tests (which, apparently, they had not deemed necessary theretofore, when making their own tests) and this, also, was done at an additional cost of $8,000.00.

At a preliminary conference had with the Pharmacological staff of F&DA in February of 1957, when all results had to that time and work still in progress were fully reported to F&DA, the pharmacologists of the independent testing laboratory in charge of those tests stated that the new color had only ten per cent of the possible toxicity of Red 32 and F&DA staff pharmacologists went so far as to concede that the new color had but twenty per cent of the toxicity of the color they had certified as harmless for fourteen years before asserting, after October 13, 1952, that it was not "harmless."

At that conference, however, Dr. Arnold J. Lehman, Chief of Pharmacological Division of F&DA, while conceding that the data then available was likewise ample for the establishment of tolerances (if authorized by the law as construed by F&DA) went on to say that the new color would not be eligible for certification "under existing regulation", (i.e., under F&DA's interpretation of the word "harmless" as requiring "zero toxicity") in view of adverse effects had at those high levels of color to food.

We have been informed by Dr. Lehman, in effect, within the past few months, that it will not be worth while for the industry to file an application for certification of the new color Citrus Red No. 2, in view of the

adverse effects shown at the higher levels of feeding, which render the color non-certifiable, according to F&DA's doctrine of "zero toxicity".

This means, of course, that neither Citrus Red No. 2, nor any other new coal-tar color, can ever be certified and that every coal-tar color presently on the list of certifiable colors must be banned, since none of said colors can meet and pass a test for "zero toxicity", when fed at 30,000 to 50,000 p.p.m. The coal-tar color industry would thus be destroyed, and the citrus industry would be reduced to chaos (R. 47-10 to 47-12).

The amounts paid to independent research laboratories for such research, to December 31, 1957, was $122,478.00, of which this Respondent has paid $22,495.60. Other development and research costs, for research conducted by color manufacturers and by the industry, in their own laboratories, comes to approximately $48,296.-14, or a grand total of $170,774.14, for research as above recited.

The alleged intent of the Congress to press the industry to undertake: (b) Scientific research which might provide "a sound factual basis for a safe tolerance for Red 32 on oranges".

The attention of the Court is again respectfully directed to the language of the Petition (p. 16) where, referring to the matter of tolerances, it is said:

> "On the other hand, **the scientific evidence to support the course of action required of the Secretary by the Court below does not now exist,** and the investigations to obtain it will involve considerable expense and require at least two years after the study is commenced."

Before any definite data as to the toxicity of the new color were available, it became known, in 1956, that the work of determining the "no effect" feeding

level of Red 32, including a "sound, factual basis for a safe tolerance for Red 32 on oranges", had already been done by qualified pharmacological experts in the laboratories of Food and Drug Directorate of Canadian Department of National Health and Welfare.

The Canadian research, now discussed, was conducted by Mr. M. G. Allmark, Chief, Pharmacology and Toxicology Section; Dr. W. A. Mannell, of that Section, and Dr. A. C. Grice, Chief, Animal Pathology Section, of the Food and Drug Directorate of the Canadian Department of National Health and Welfare.

Their article entitled: "Part 2: Observations on The Toxicity of FD&C Green No. 2 (Light Green S. F. Yellowish; FD&C Orange No. 2 (Orange SS) and FD&C Red No. 32 (Oil Red XO) In Rats", **was released on January 10, 1956 and published in June, 1956, in** "The Journal of Pharmacy and Pharmacology", Vol. VIII, No. 6, "By Direction of the Council of the Pharmaceutical Society of Great Britain, 17 Bloomsbury Square, London, W.C.I."

(Since the article was dated January 10, 1956, and related to a matter then being pressed by F&DA, there is no reason to assume (since the closest of relations exist between the two bureaus) that Canadian Food and Drug Directorate did not make these data available to U.S. F&DA not later than January 10, 1956. In any event F&DA knew of the existance of incontestable "scientific evidence" in June of 1956.)

A photostat of reprint of that article is in the Appendix (pp. A8-15) and we respectfully request the particular attention of the Court to the graph curves at pp. A-9 and A-11 and to conclusions reached as recited on p. A-15 thereof, under "Summary", which read:

> "1. FD&C Orange No. 2, FD&C Red No. 32 and FD&C Green No. 2, in concentrations of 0.03 per cent (300 p.p.m.) in the diet did not affect

growth, food consumption, or food efficiency in eiher male or female rats."

"2. In groups receiving FD&C Orange No. 2 and FD&C Red No. 32 in concentrations of 0.75 per cent (7500 p.p.m.) and 1.5 per cent. (15,000 p.p.m.) in the diet, there was 100 per cent mortality before the completion of the experiment."

"3" (Omitted. — Relates to FD&C Green No. 2 only)

"4. Haemoglobin production was not affected by 0.03 per cent (300 p.p.m.) in the diet of either FD&C Orange No. 2 or FD&C Red No. 32, but oral doses of 200 and 400 mg/kg. of these two colours caused a decline in haemoglobin values which was significant in both sexes at 20 weeks.***"

"5 The only significant pathology was found in the tests of those rats receiving a dietary level of 3.0 per cent (30,000 p.p.m.) or an oral dosage of 400 mg/kg. of FD&C Red No. 32." (Parenthetical matter supplied in all).

(To ingest, from eating Color Added oranges, the daily oral dosages of 200 and 400 mg/kg of Red 32 given these rats a human would have to eat, daily, 1750 and 3500 Color Added oranges, respectively, peel and all, or drink 5,000 gallons, daily, of the juice therefrom . . . Ill effects are to be expected from feeding levels of 7500 and 15,000 p.p.m.)

The tests ran 66 weeks, — 465 days. (See Table III Ap. A-10) F&DA considered their 173 day tests (JA. 87) ample to offset 1938-1944 tests by F&DA that ran for 64 to 73 months. (JA 85-86). The Canadian report will likely be accepted by everyone in the scientific world except F&DA, who would have this Court believe, two years later, that "the scientific evidence necessary" (to

establish tolerances) "does not now exist." (Petition, p. 16)

The colors having Canadian designations of "Orange I" (U. S. FD&C Orange No. 1) "Orange S.S." (U.S. FD&C Orange No 2) and "Oil Red XO" (U.S. FD&C Red No. 32) (the three colors decertified by the Secretary's Order) had been on the Canadian list of approved colors for some years, and maximum use limits (tolerances) had been established therefor under Canadian Food and Drug Regulation B.06.004, which reads as follows:

> "B.06.004. No person shall sell a food, other than a coal-tar colour, having in it or upon it an added coal-tar colour for which a standard is provided in B.06.001 to B.06.038, if the proportion thereof exceeds one part by weight of coal-tar colour to each thirty-five hundred parts by weight of food, as prepared for consumption according to label directions."

The tolerance thus prescribed is equivalent to 286 parts per million. Those colors were found to be harmless at 300 parts per million (Oranges contain 4 p.p.m.).

The Canadian research work on FD&C Green No. 2, FD&C Orange No. 2 and FD&C Red No. 32 was doubtless a recheck to verify the validity of those tolerances. It was completed in 1955 and, as shown, no adverse results were noted and the colors remained, for some months thereafter, on their list of approved colors.

However, by Canadian Order in Council dated July 26, 1956, the three colors FD&C Orange No. 1, FD&C Orange No. 2 and FD&C Red No. 32 were removed from the approved list, which, of course, means that Florida and Texas Color Added oranges have been excluded from Canadian markets since October 1st, 1956, another serious blow to the industry of those states, flowing from the unlawful action of FD&A.

The only official reason ever stated for the Canadian ban on Red 32 is contained in the following statement made by Hon. Paul Martin, Minister of National Health and Welfare, in the House of Commons, on July 27, 1956, as reported by "Hansard" (Canadian equivalent of our Congressional Record):

> ***"I shall simply say, in addition to what I have already said, that in taking the steps that we did with regard to the particular colour in oranges the ban applies as of August 1. **It was not because we had found dangerous levels of colour in oranges in Canada but because we simply wanted to take a precautionary step.**
>
> "In the regulations under the Food and Drug Act, provision was made for the use of 17 coal-tar colours in foods. In addition **there is a requirement that the maximum amount of colour to be used in any food is limited to one part per 3500 parts of food or approximately 0.03 per cent.** In surveys which have been conducted in the food and drug laboratories of our department, it has been found that this level is reached in only a few foods, and **the level of colour in the majority of foods, where it is used, varies from one to two parts per 100,000 parts of food.** At the time the permitted list of coal-tar colours was established and with the evidence then available as to the safety of their use in foods, no indication of harmful effects was evident. **Moreover, no reports have come to the attention of the food and drug directorate that the ingestion of foods containing any of the colours in amounts permitted in Canada has caused harmful effects in humans.** However, my hon. friend may be assured that this matter will continue to receive the attention of our officials in the food and drug division

in connection with our own work, **along with that particularly carried on in the United States.** (Emphasis Supplied).

It seems apparent from Mr. Martin's remarks that Canada decertified Red 32, as a "precautionary step", on July 26, 1956, after and, probably, because U.S. F&DA had ordered the decertification thereof on November 10, 1955, since he thereafter gave the same colors a clean bill of health in his remarks in Commons where, as will be noted, it was the use thereof on oranges that was in question.

The attention of the Court is also respectfully directed to Mr. Martin's statement that few foods contain the maximum amount of color permitted under Canadian regulations (1:3500 being 286 p.p.m.) that in the majority of colored foods the color content varies from "one to two parts per 100,000", i.e., 10 to 20 p.p.m. (oranges, 4 p.p.m.).

It should be noted, also that Canada has had no trouble in making those determinations as to tolerances for coal-tar colors, when necessary to protect the public health, which F&DA would have the Courts believe is, for them, an impossible task.

In view of the foregoing it is respectfully submitted that Canada has already done the work necessary to prove the harmlessness of Red 32 for use in all foods, and to establish, for U.S. F&DA, "a sound, factual basis for a safe tolerance for Red 32 on oranges," supported by authoritative "scientific evidence."

We regret that the necessity for discussion of these errors in the Secretary's Petition added 13 pages to an already lengthy brief.

The 1953 Tests of Red 32 As Made By F&DA

We comment on these tests here, although not strictly pertinent at this time, only because the Pe-

tition-Brief states conclusions allegedly based thereon as though the same were proven facts (PB 7-9).

These tests (JA 86-93) ran for 173 days only, and are, of course, offered to offset the results of F&DA tests over 64 to 73 months (1938-1944) (R. 85-86) upon which tests the colors was certified as "harmless and suitable for use in food."

The witness for **the color industry** testified (JA 49) that he accepted the "results" of tests made by F&DA, and this has been cited in the Petition (PB 6-7) as though the witness had testified that he accepted "the conclusions attempted to be premised upon the results of tests made by F&DA", — which he did not imply. Such testimony by that witness for **the color industry** is not properly citable as against the citrus industry or this Respondent.

We will not enter into an extensive discussion of the merits of those tests, vulnerable though they are (R. 243-249, 253, 257) but merely call attention of the Court, in passing, to these points only:

(a) In the tests made by F&DA in 1938-1944, the color and feed were administered separately (R. 85) which feedings methods did not create in the dogs an antipathy for their food. In those tests weight losses from higher levels of color dosage were recovered and the animals finished 64 to 73 months of feedings at levels of as high as 20 mg/kg, (800 ppm) and as low as 5 mg/kg (200 ppm) in good condition (JA 85) showing no adverse effects chargeable to color (JA-86).

(2) In the 1953 tests (JA 87) the color dosage was mixed into the feed given the dogs, which would, of course, create an antipathy, even an allergy, as regards that feed, causing the dog to refuse it, when they suffered diarrhea from such feed, as they did (R. 87). All dogs showed "emaciation" (from "slight" to "extreme" 'JA.

92) at the end of these tests — but the Record is significantly silent as to comparative food consumption and weight figures as between dogs receiving colored and uncolored food.

(3) We respectfully request the attention of the Court to these facts in the case of the one dog that died after 173 days on a diet containing color at 100 ppm., having lost 60% of its body weight and showing "dehydration" (JA 87-89) indicating a refusal of both food and water at the end:

(a) This dog's test was the basis for the Secretary's "Conclusion" No. "4"; "No safe level of administration was found even in test animals for FD&C Red No. 32."

(b) This dog was first put on a diet containing color at 2000 ppm. mixed in its food, and kept thereon until it had lost 24% of its body weight, then with another dog that had lost 19% of its body weight on the same diet, in the same length of time, was put on a color free diet 'for about 10 days', during which time both dogs "regained some weight and improved their physical condition." (JA 87). Then those two dogs, with "two additional dogs", went on this diet containing color at 100 ppm. and at the end of 173 days the first dog died, but the other three dogs "lost some weight but appear in fair condition after nearly 10 months on this level" (JA 87).

(c) These results prompt a question as to why the Secretary bases his above quoted conclusion on the alleged effect on the one dog that died, instead of on the three that tolerated the colored food.

(d) In the absence of comparative figures for food consumption and weight as between dogs on colored and uncolored food, it is impossible for anyone to say whether the adverse effects resulted from refusal of the colored food because (a) it was (1) unpalatable, or (2) induced illness, or (b) were due to an acute allergy developed from

feeding color at the 2000 ppm. level (almost certainly true of the dog that died) or (c) to actual toxicity of the color. Absent such data as to food eaten, any conclusions based on these tests are sheer guess-work, completely worthless. We could contend, with more logic, that the dog died of starvation, unhurt by the color because he would not eat the food containing it.

(e) The figures for the 4 dogs on a color ration of 400 ppm. mixed into their feed (JA 87) are contradicted by the Canadian results, before discussed (p. 20-22 supra) and of the dog on 800 ppm. color feeding in 1938-1944 (JA 85) which strongly indicate that the adverse effects resulted from mixing the colors in the feed, inducing food refusal and consequent malnutrition.

ARGUMENT

Legislative History Of The Act.

We now respectfully submit that the legislative history of the Act makes it very clear (1) that Congress used the word "harmless" in its relative sense and not in any "absolute" sense as contended by F&DA and (2) that the Congress mandatorily required the Secretary to establish tolerances for coal tar colors under Sec. 406 (a)

Prior to the 1938 Act, there was no specific statutory use of the word "harmless". The various regulations relating to coal-tar food colors were issued by F&DA under the general language of the 1906 Act, which provided that food would be deemed to be adulterated.

> "• • if it contains any added poisonous or other added deleterious ingredients which may render such article injurious to health." (F&D Act of 1906; Sec. 7, 34 Stat. 769) (Emphasis supplied.

However, use of the word "harmless", in the regu-

lation of coal-tar food colors, goes back to the first coal tar color regulations ever issued on such colors under authority of the 1906 F&D Act, being Regulation 12 and 13, Bureau of Chemistry, 1907, which were reissued, in 1927, as Regulation 13, reading:

> "(a) Only **harmless** colors and **harmless** preservatives may be used in articles of food." (originally Reg. 12).
>
> "(b) A color, preservative, or other substance, even though **harmless**, shall not be used in the preparation of any food in a manner whereby damage or inferiority is concealed." (originally Reg. 13). (Emphasis ours).

The same or equivalent language was carried forward in reissues of such regulations and remained in effect (See Dunn. p. 1348) until the 1938 Act was enacted, when the word "harmless" was merely transplanted into the Act, in Subsection 406 (b), reading:

> "(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are **harmless** and suitable for use in food and for the certification of batches of such colors, with or without **harmless diluents.**" (Emphasis ours).

The purpose and intent of the Congress in enacting section 406 (b) was stated in clear cut and direct terms. From the first hearing on the bill S-1944 (73rd Congress, 1st Session, 1933, see Dunn, Ap. B, p. 1066) until the final mention of the section in the House Report on Bill S-5 as enacted (75th Congress, 3d Session, 1938, see Dunn, p. 820) that purpose and intent was emphasized repeatedly, as being:

> **"This continues in effect a system of certification which has been followed almost from the beginning of the enforcement of the old food and**

drug law" • • •,. (Dunn, p. 820, emphasis ours).

When read in the light of that statement, there is not a word in the legislative history of the Act which supports the contention of F&DA herein that the Congress intended to limit certification of coal-tar food colors to those that were "harmless" in the absolute sense of that word. Until at least October 13, 1952 (R. 72) F&DA were statedly of the same conviction.

Since Orange 1, decertified by the order appealed from, and Yellow OB (FD&C Yellow No. 4) and Yellow AB (FD&C Yellow No. 3) (now sought to be decertified per "Proposed Rule Making" published in Federal Register for May 4th, 1957, p. 3173), are three of the colors certified in those early days, it is apparent that the word "harmless" was always used in its "relative" sense, since certification would have been prohibited if the word "harmless" had been used in its "absolute" sense.

Since five years have elapsed since F&DA made its initial attempt in 1953 to construe the word "harmless" in an "absolute" sense, rather than the "relative" sense theretofore followed, and since 12 coal-tar colors, all containing such poisons, are still on the certified list and unchallenged as to their "harmlessness", it follows that F&DA is still construing the word "harmless" in its "relative" sense insofar as those 12 coal-tar colors are concerned.

We now further respectfully submit that, specifically, the last amendments to Sec. 402 (c), 406 (a) and 406 (b), prior to enactment of the Act, make it very clear that each of those amendments were enacted pursuant to a very evident purpose and intent of the Congress to insure the continued use of coal-tar colors for coloring citrus fruit.

The pertinent parts of the bill "Senate 5 — 75th

Congress" as it passed the Senate on March 9, 1937, (Dunn, p. 746) read as follows:

Sec. 11 (enacted as section 402) then read:

"Sec. 11. A food shall be deemed to be adulterated;

"(c) If it contains a coal tar color other than one from a batch that has been certified in accordance with regulations as provided by Section 15." (Dunn 782).

Sec. 15 (enacted as Sec. 406) then read:

"Sec. 15 (a) Any contaminating, poisonous, or deleterious substance added to any food, except when such substance is required in the production thereof or cannot be avoided by good manufacturing practice, shall be deemed to be unsafe for purpose of the application of section 11 (a), but when such substance is so required or cannot be so avoided, the Secretary **is authorized** to promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of the public health. • • • .

"(b) The Secretary **is hereby authorized** to promulgate regulations for the certification of coal tar colors which are harmless and suitable for use in foods." (Dunn, p. 785). (Emphasis ours)

The Bill went to the House Committee on Interstate and Foreign Commerce on March 10, 1937, where it remained until August 20th, 1937, when that Committee presented to the House a revised bill (Dunn, p. 751) arrived at by striking everything in the Bill as passed by the Senate except the Title and enacting clause and inserting a House Committee draft.

We find these amendments in this new House draft of the bill, reported on August 20th, 1937, in the sections here concerned:

"Sec. 402. A food shall be deemed to be adulterated—

"(c) If it **bears or** contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: **Provided, that this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this act for the purpose of coloring citrus fruit."** (Emphasized matter is amendment concerned).

"Sec. 406 (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of **clause (2) of** section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary **shall** promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for the purpose of the application of **clause** 2 of Sec. 402 (a). **While such a regulation is in effect, limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of Sec. 402 (a)** * * *". (Emphasized matter indicates amendment concerned).

"(b) The Secretary **shall** promulgate regu-

lations providing for the listing of coal tar colors that are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents." (Emphasized matter indicates amendment concerned).

The purpose and intent of the Congress in adding the "proviso" clause to Sec. 402 (c) is crystal clear. The language used is susceptible of but one interpretation — that coal-tar colors were then being used to color citrus fruit, which practice enjoyed Congressional approval; that application for certification of a color so used had been made but had not been acted upon by the Secretary; that to the end that such coloring practice be not stopped or interfered with by the failure or refusal of a Secretary to certify needed colors, Congress was granting special authority for the continued use of that color until the application for certification thereof had been acted upon by the Secretary.

When the corollary amendments to Section 406 are considered in the light of the addition of that "proviso" amendment to Section 402 (c), the purpose and intent of the Congress in enacting those amendments is likewise crystal clear.

As admitted by the Secretary's petition (PB. 19, lines 7-9 of designated par. "A", and cited authorities) Congress was fully informed and advised that: "Coal tar colors have always been recognized as having potentialities of danger." Those coal-tar colors were known to contain small amounts of arsenic and lead, together with other deleterious substances produced by side reactions during manufacture (see F&DA Coal-Tar Color Regulations, p. 46-47).

Coal-tar colors containing such poisonous or deleterious substances were, therefore, clearly within the interdiction of section 402 (a) unless tolerances were prescribed therefor. So long as the statutory power to

fix tolerances and certify colors was permissive or discretionary with the Secretary, the use of coal-tar colors for the coloring of citrus fruits could be stopped or interfered with by the failure or refusal of a Secretary to establish necessary tolerances therefor, or to certify needed colors.

The Congress, therefore, pursuant to its purpose and intent, so clearly evidenced by the amendment to section 402 (c), to insure the continued use of coal-tar colors for coloring citrus fruit, amended Section 406 (a) by changing the permissive "the Secretary is authorized" to the mandatory "the Secretary **shall"** and by spelling out the exemption accorded to foods containing such tolerated amounts of deleterious substances.

Pursuant to the same intent, Congress also amended Section 406 (b) by again changing the permissive "the Secretary is hereby authorized" to the mandatory "the Secretary **shall".**

That the amendments to Sections 402 (c) and 406 (b) are of the same origin and purpose is further evidenced by the fact that the proviso amendment to section 402 (c) and section 406 (b) both refer to the "listing" of certifiable colors, "listing" being a word never before used in the proposed legislation.

It is further to be noted that nowhere in the Act did Congress mention a specific food by name, except in the "proviso" amendment to Section 402 (c) re coloring of citrus fruits, which is indicative of the importance attached thereto by the Congress.

Although these amendments were of decided importance, especially to F&DA, Dunn reports no reference whatever to those amendments in any Report or Debate on the Act. The majority Report to the House (Dunn, p. 819-820) and the Minority Report (Dunn, 834) are silent thereon, and there is no mention thereof in the

prolonged debate in the House (Dunn, 840-963) nor, the Senate having refused to agree to another House amendment, in the Conference Report and statement in the House (Dunn, 970-996). There was no debate in the Senate on either the House re-write or the conference report.

It seems obvious, therefore, that the amendments were accepted as non-controversial by the Congress, and were so enacted. The reason for the lack of controversy will be found at R. 227-228.

We will now discuss the four questions suggested:

(1) **Whether there is any basic conflict between the decision of the Circuit Court of the Second Circuit and the decision of the Circuit Court of the Fifth Circuit.**

We now respectfully show to this Court that there is no basic conflict between the decision of the Second Circuit Court and the decision of the Fifth Circuit Court that would warrant review by this Court, because, first:

(A) **The parties were not the same.**

(B) **The record was not the same.** The record before the Second Circuit Court consisted of no more than:

(1) Notice of hearing set for January 19, 1954 (R. 52 herein);

(2) Excerpts from testimony and exhibits introduced at that hearing;

(3) Notice of Proposed Rule Making, issued in December, 1954 (R. 53);

(4) Exceptions thereto of Coal-Tar Color Industry Committee (R.82);

(5) Secretary's Final Order of November 10, 1955 (R. 281-282);

(6) Coal-Tar: Industry petition to reopen Proceedings (R. 259);

(7) Order denying that Petition (R. 262).

The record before the Second Circuit Court did not contain the Exceptions and arguments thereon as filed by the Florida and Texas Citrus Industry (R. 158-207 herein) nor those of this Respondent (R. 209-259 herein), nor those of four other parties to the Department proceedings. The Second Circuit Court, therefore, had before it a case that was related to the instant case, but as to which the record was fragmentary and misleading, containing but few facts as to the issue before the Fifth Circuit Court.

Moreover, the record before the Second Circuit Court contained no information whatever as to the use of Red 32 on oranges save the analyses of amount of color deposited in the peel of an orange and in certain by products (herein at JA 44-45).

(C) The issues were not the same.

In the Second Circuit Court the issue was whether, on the abbreviated record before that Court, the Secreary's Order, which delisted three colors (Orange 1, Orange 2, and Red 32) prohibiting their general use in **all** foods and **all** drugs taken internally, should be sustained. The question of whether an exception might be made, permitting the use of Red 32 on oranges only (the issue here) was not before that Court, yet the Court said (A-7) that the coloring of oranges presented a different problem.

The issue before the Fifth Circuit Court was whether, on a more complete record, and in view of the precise data presented as to amounts of color used in or on oranges and in by-products thereof, and other pertinent data not before the Second Circuit Court, the facts and the law warranted an exception, **under** (but not contrary to) the decision of the Second Circuit Court, so as to permit the continued use of Red 32 for no other pur-

pose save coloring the peel of oranges, where, as was admitted by F&DA, such use poses no danger whatever to public health.

The Fifth Circuit Court decision did not imply that the decision of Second Circuit Court was in error. Instead, the validity of that decision, on the broad general question before it, was explicitly concurred in by the Fifth Circuit Court. That Court, on a better record, merely settled a point (tolerances) which the Second Circuit Court did not see fit to pass upon.

In our further argument we will discuss the three questions presented to the Fifth Circuit Court and demonstrate that the Fifth Circuit Court was correct in deciding these questions and that, in deciding the questions, the Fifth Circuit Court expressly held that it was not deciding said questions in conflict with the Second Circuit Court but, on the basis of the facts before the Fifth Circuit Court, provided for certain exceptions to the general rule established by the Second Circuit Court.

We will now proceed with argument on the three questions presented to the Fifth Circuit and, in our argument on these three questions, will consistently show that there is no basic conflict between the decisions of the two Circuit Courts.

(2) Whether the Circuit Court, Fifth Circuit, erred in holding that Red 32 is "harmless and suitable for use in foods" for coloring of oranges only, within the contemplation of the Food, Drug and Cosmetic Act.

The fundamental question before both the Second Circuit Court and the Fifth Circuit Court was the purpose, meaning and intent of Congress in the use of the word "harmless" in Section 406 (b) of the Act.

In both lower Courts the appellants contended

that the word "harmless" was to be construed in a "relative" sense and in both cases the Secretary contended that the word "harmless" was to be construed in its "absolute" sense.

Both Courts devoted a considerable portion of their respective opinions to this point.

On this point the **Second Circuit Court** said:

> "Petitioners argue that the 1938 amendment, insofar as those sections are concerned, amounts to nothing more than legislative recognition of existing practice and procedure; that the word 'harmless' must be equated to 'added poisonous or other added deleterious ingredients which may render such article injurious to health' and that these words must be given the meaning assigned to them in **Wood Mfg. Co. v. United States**, 286 Fed 84 (7th Cir. 1923). The **Wood** case adopted a standard of relativity and held that an infinitesimal quantity of arsenic in a coal-tar color was not a poisonous or deleterious substance, injurious to health as ordinarily used, and that the Government was required to prove that the substance was in fact injurious as used. Respondent, on the other hand, urges that the use of a different word — 'harmless' — instead of the more familiar statutory language is evidence of Congressional intent to provide an absolute standard. **We are unable to agree with either of these interpretations.** (Emphasis ours)

The Second Circuit Court decision goes on to state that because Congress, in the Act, dealt separately with (a) poisons inherent in food and (b) poisons added to food, this indicated Congressional discontent with the **Wood** case, and

> **"a return to the principles enunciated by the Supreme Court in United States v. Lexington Mill**

and Elevator Company (232 U.S. 399) wherein it was said:

> "It is not required that the article of food containing added poisonous or other added deleterious ingredients must affect the public health, and it is not incumbent upon the Government in order to make out a case to establish that fact. The act has placed upon the Government the burden of estabilshing * * * that the added poisonous or deleterious substances must be such as may render such aricle injurious to health.
>
> ***In thus describing the offense Congress doubtless took into consideration that flour may be used in many ways, in bread, cake, gravy, broth, etc. It may be consumed, when prepared as a food, by the strong and the weak, the young and the old, the well and the sick; and it is intended that if any flour, because of any added poisonous or deleterious ingredient, may possibly injure the health of any of these, it shall come within the ban of the statute. **If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under this act'**
>
> "By restricting the ordinary usage test to non-added substances, the inference is inescapable that Congress meant to similarly restrict the **Wood** case and to correspondingly restore the doctrine of the **Lexington Mill** case * * *."

In the **Fifth Circuit Court decision,** the Court said:

> "The words 'harm', 'harmful', and 'harmless'

are terms of relation. In this sense they resemble 'wrong' and 'wrongful'. Red 32 is harmless, i.e. not harmful, to all persons under the protection of the Act, while it remains in the vat or vial. An injury must occur before harm results. The color Red 32 becomes harmful, i.e. not harmless, when it is consumed, and then only if consumed in such quantity that injury or harm might result. If there can be a use of the color in such quantities that it can be consumed without risk of injury or harm then, in such quantities, it is harmless. A person is as unharmed after consuming a minute harmless quantity of Red 32 (if such there be) as he would be had he consumed none of it.

"In **United States v. Lexington Mill & Elevator Co.**, supra, the Supreme Court reviewed the condemnation of a lot of flour to which had been added a poisonous ingredient but in a quantity so small that the health of a consumer could not be thereby injured. The statute then provided that an article of food should be deemed to be adulterated if it 'contain any added poisonous or other added deleterious ingredient which may render such article injurious to health'. **It was contended there, as it is contended here, that it is the character — not the quantity — of the added substance which is to determine the case. The contention was rejected. The Court said:**

> **"'If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act.' 232 U. S. 411.**

"As in the Lexington Mill case, it was held in the Seventh Circuit that 'injurious' is a relative

rather than an absolute term. **W. B. Wood Mfg. Co. v. United States,** 7 Cir. 1923, 286 F. 84. We think 'harmless' is also to be so construed."

Thus the Second Circuit Court and the Fifth Circuit Court, while differing somewhat in their approach, arrived at the same conclusion, both holding that the word "harmless" should be construed in the light of this holding by this Honorable Court:

> "If it cannot by any possibility, **when the facts are reasonably considered,** injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the Act." **(U.S. v. Lexington Mill** supra) (Emphasis Supplied)

We respectfully inform this Court that this Respondent has never asked more than that F&DA observe those guiding words of this Court, which fairly reflect the intent of the Congress.

We next respectfully submit that since both the Second and Fifth Circuit Courts rejected the Secretary's contention that the word "harmless" must be construed in its absolute sense, and held that, instead, the construction thereof should accord with the rule laid down by this Court in **U.S. v. Lexington Mill & Elevator Co.,** it would appear that the real prayer of the Petition is that this Court overrule (not reconcile) not only the decisions of both the Second and Fifth Circuit Courts, but the cited decision of the Supreme Court as well.

(3) Whether the Circuit Court, Fifth Circuit erred in holding that the Secretary had the authority under the Federal Food, Drug and Cosmetic Act to fix tolerances for use of coal-tar colors on or in specified foods.

The next question that was presented to both the Circuit Courts was the question of whether or not the Secretary had authority to establish tolerances for use of coal-tar colors.

Both courts devoted a considerable portion of their respective opinions to this point.

The **Second Circuit Court** decision, on this point said:

> "**The subsidiary question** raised by the denial of a rehearing, **relating to the Secretary's authority to impose tolerances** under which the colors may continue to be used **need not be answered. All we need decide is whether or not petitioners can require him to establish such tolerances. Under the circumstances disclosed in the record we hold that they have no right to do so.** There are two reasons for this. In the first place there is nothing in the record to indicate how much of these coal-tar colors a human being could ingest over a period of years without any harmful effects, nor did petitioners propose to introduce any. The respondent's conclusion in this connection is as follows:
>
> 'While a safe level of administration to test animals is disclosed by the record in the case of FD&C Orange No. 1, the record also discloses that the color has adverse effects upon man at a level well below the safe level of administration to test animals. The safe level of administration of FD&C Orange No. 2 to test animals is well below the level at which FD&C Orange No. 1 was found safe to test animals. It is therefore, even more toxic than FD&C Orange No. 1. No safe level of administration was found even in test animals for FD&C Red No. 32'.

> "Furthermore, it may be impossible to demonstrate the precise cumulative effect over 20 or 30 years of consumption of specified amounts of color and therefore impossible to prescribe safe tolerances. We think that the Secretary's findings that such tolerances cannot be determined should be accepted and that they are dispositive of the case."

Rather than add four more pages to a too long brief, we respectfully make reference to that part of the Fifth Circuit Court's decision having to do with tolerances, which appears in Appendix to the Secretary's Petition, beginning with first paragraph at top of p. 40 and extending through last complete paragraph on p. 43 thereof.

As shown, the Second Circuit decided only that Petitioners could not require the Secretary to establish tolerances **in that case "under the circumstances disclosed in the record"**, because there is nothing in the record to show the amounts of Red 32 that can be consumed by humans without harmful effect and nothing to show the amounts in different food.

That language does not in anywise imply that in a case where it is shown to the Court (as it was shown in the Fifth Circuit Court) that the amount used to color a specific food is so small as to be harmless in the amount used, but may be harmful when consumed in larger amounts, the Secretary cannot be required to establish a tolerance therefor if necessary in order to protect the public health. Indeed, the Second Circuit Court decision pointed out the difference between a case such as was before that Court, involving, as it did, the use of all colors on or in all articles of food, drugs and cosmetics, and a case where only oranges are concerned, saying:

> "Thus the problem is far different from the one presented recently to Congress when the act was amended to permit the use of Red 32 on orange skins not intended for processing. With only one product contaminated it was not too difficult to argue that such small amounts were involved that a man would have to drink 5000 gallons of orange juice a day before experiencing any adverse effects. Hearings Before the Subcommittee on Interstate and Foreign Commerce, 84th Cong. 2d Sess. at 13 (1956)."

The Secretary admits (under "A", PB. 19) that Congress was informed and advised, as far back as 1933, that "coal-tar colors have always been recognized as having potentialities of danger", but complains:

> "In contrast to the Second Circuit the ruling below does require the Secretary to establish tolerances unless he affirmatively proves that the Court's assumption as to the safety of Red 32 is wrong. In short, the Court below has given its stamp of approval to an acknowledged poison and cast the burden on the Secretary to show that the coloring is not safe for oranges." (PB 15).

We respectfully submit that it is the Statute, (Sec. 402 (c)) and not the Court below, which imposed upon the Secretary the mandatory duty of establishing tolerances for a color which is entirely safe in the amounts and for the purpose used, but may be harmful when used in large quantities. The Fifth Circuit merely applied the Statute as it is written.

It should be noted, in passing, that the Second Circuit Court decision affirmatively discloses that the Court misread Section 402 (c) of the Statute, the Court saying:

"Section 402 (c) (21 U.S.C. 342 (c)) was added to deal specifically with the problem of coal-tar colors. It provides flatly that a food shall be deemed adulterated if it contains a coal-tar color other than one from a batch certified under Sec. 406 (b), ***"

whereas the statute reads "other than one from a batch certified under Section 406" — not 406 (b), or 406 (a), but under 406 in its entirely — not just a part thereof.

Sec. 406 is made up of Secs. 406 (a) **and** 406 (b) and when the Congress said that a color must be from a batch certified under Section **406**, that means of course, **under Subsection 406 (b) and under Subsection 406 (a).**

It seems clear, therefore that the Congress mandatorily required the Secretary to establish tolerances, under Section 406 (a), for coal-tar colors certified under Section 406 (b), if such tolerances are necessary to protect the public health.

Moreover, the Secretary has affirmatively recognized that mandate and the relationship between Sections 406 (a) and 406 (b) **and since enactment of the 1938 Act has exercised, and to this day continues to exercise, his authority to fix tolerances for food colors under the authority of Sec. 406 (a).** He has, since 1940, prescribed the amounts of deadly poisons permissible in coal tar colors intended for use in foods, **using the very language of Section 406 (a),** which prohibits added deleterious substances in food except where necessary in production or impossible to be **"avoided by good manufacturing practice."**

We respectfully call the attention of this Court to the following provisions of F&DA Coal- Tar Color Regulations, Section 135.02 whereof reads, in pertinent part:

"Section 135.02. **General Specifications For Straight Colors."**

No batch of a straight color listed in Section 135.03, 135.04, or 135.05 shall be certified under these regulations **unless—**

"(a) **It is free from all impurities (other than those named in paragraph (b) or in the specifications** set forth in such section for such color) **to the extent that such impurities can be avoided by good manufacturing practice.**

"(b) It conforms to the following specifications:

(1) In the case of a straight color listed in section 135.03—

Lead (as Pb), not more than 0.001 per cent.

Arsenic (As^2O^3), not more than 0.00014 per cent.

Heavy metals (except Pb and As) (by precipitation as sulfides), not more than trace." (Emphasis ours).

Under Sec. 135.03 (pp. 3-8) of those same Coal Tar Color Regulations, under the provisions of tolerances clause (a) above quoted, tolerances are fixed in the specifications for 18 colors (listed as certifiable for use in food, drugs and cosmetics) strictly limiting the permitted maximum amounts of still other deleterious substances, as, for example, in FD&C Red No. 32 (pp. 6-7) which provides:

"FD&C Red No. 32

"Specification

"1-Xylylazo-2-naphthol.

Volatile matter (at 100° C.), not more than 0.5 per cent.

Sulfated ash, not more than 0.3 per cent.

Water soluble matter, not more than 0.3 per cent.

Matter insoluble in carbon tetrachloride, not more than 0.5 per cent.

Xylidine, not more than 0.1 per cent.

beta-Naphthol, not more than 0.05 per cent.

m-Xylidine in xylidine obtained by reduction of the dye, not more than 30.0 per cent.

Pure dyle (as determined by titration with titanium trichloride), not less than 97.0 per cent.

Boiling range of xylidine, obtained by reduction of the dye, 95 per cent between 212-232° C."

Yet, after 19 years of thus observing and invoking the provisions of Section 406 (a), in relation to coal-tar colors certified under 406 (b), F&DA has argued before two Courts of Appeals that F&DA has never seen any connection between the provisions of Sections 406 (a) and 406 (b) of the Act.

Yet, very obviously, the Secretary has always used the word "harmless" in its relative sense, is still so using it and, so long as Secs. 135 02 and 135.03 of F&DA's "Coal-Tar Regulations" remain in effect will continue to so use that word in its relative sense, because, absent such construction, and absent that relationship between Subsections 406 (a) and 406 (b), a coal-tar color containing the tolerated content of lead, arsenate and other heavy metals prohibited by Sec. 406 (a), clause 1, would be completely illegal, because the same could not possibly be "harmless" under F&DA's doctrine of "zero toxicity".

Again, Findings of Fact 10 reads (R. 282):

"10. There was no evidence on which findings could be made concerning how much of the three colors is likely to be ingested by man from his food, drugs and cometics. Some interested

> **persons, taking their own products, attempted to show that the the amounts ingested would be small to the point of insignificance. But those contentions leave aside the occurences of the colors in the products of others, as well as the fact that upon certification of a color the Department has no means of controlling the amounts of colors used in a variety of food, drugs and cosmetics. Nor is there authorty to limit a color, once certified, to a single food — for example, FD&C Red No. 32 for use in color-added oranges.** (R. 2021, 67-68, 98-108; Ex. 8.)" (Emphasis supplied).

We ask that the Court compare that language, written for the Secretary by F&DA, when seeking to avoid the power to fix tolerances for coal-tar colors which they admit are harmless in the amounts used in oranges, with the language used by Mr. W. G. Campbell, Chief of F&DA, when testifying before the Senate Committee on Labor and Commerce on December 7th, 1933, in behalf of Section 10 (a) of Senate Bill 1944, which F&DA vigorously contended for when they **wanted** power to fix tolerences for "added poisons" and "added deleterious substances" in food, as in Section 406 (a) as enacted. Then Mr. Campbell testified:

> "This is an extremely important, in fact, one of the most important provisions of this bill. **It may be impossible to preclude absolutely poisonous ingredients from food. Some of the deleterious ingredients with which we have to deal are to be found universally. But it is important that they not only be kept to such a low limit in each article of food in which they may be found that that article of food itself may not be dangerous to health, but important, furthermore, that the total intake of poisons by the consumer of**

foods from all sources be restricted to an amount which will not be dangerous to health."

• • • •

But, Mr. Chairman, and this is another important argument for this particular paragraph, under the terms of the present law we are able to consider only a single commodity. If that single article of food does not contain poison in excess of the tolerance that has been determined as safe for consumption, it is not in violation of the present law. But suppose that article contains just a little less than the safe tolerance. Multiply that by the number of articles of food also containing traces of added poisons which constitute our daily diet, and you can get some conception of what the general intake of poisonous substances would be.

"Now, while there is an economic need for the use of poisonous sprays, **there is no justification at all for the appearance of those poisonous ingredients in a great many food products."** (Dunn, App. B, pp. 1056 - 1057; Emphasis ours)

Thus, when F&DA, in 1933, was seeking, from the Congress, the power to establish and enforce tolerances on all poisons and deleterious substances, F&DA's argument was that such substances are found in so many foods that the aggregate consumption of such substances could be dangerous to public health, making it imperative that F&DA be empowered to establish and enforce tolerances therefor which would take into account the total of all of such substances that a consumer might ingest in all of his food.

But now, F&DA asserts that it is impossible for it to establish tolerances on coal-tar colors which it concedes are harmless in amounts consumed, because so many foods contain those coal-tar colors.

This self-contradictory contention by F&DA was disposed of by the Fifth Circuit in these words:

> "The Secretary, in his Order, has stated that 'the Department has no means of controlling the amounts of colors used in a variety of foods, drugs and cosmetics'. It is not apparent that this is a problem with respect to other toxic substances which are added to foods, under tolerances fixed by the Secretary and nothing is shown to indicate that it would be a problem in dealing with a coal-tar color." (Petition, p. 42)

Again, at "B"; Page 21, the Petition says:

> "B Even assuming that coal tar colors could come within the scope of the 'tolerances' provision of Section 406 (a), the Fifth Circuit has misinterpreted that section in holding that 'required in the production' means 'required in the production for market' by a particular industry, • • •."

Throughout this litigation F&DA has insisted that oranges are food and the law must be applied to oranges as to any other food, but now it insists that oranges are a thing apart from the general classification of foods and that production ceases when the fruit is ready to harvest.

But Section 406 (a) reads:

> "Any poisonous or deleterious substance **added to any food** except where such substance is **required in the production** thereof **or cannot be avoided by good manufacturing** practice • • •."

If the "production" of oranges ceases when the fruit is ready to harvest, the fruit must still be prepared for consumer consumption and, obviously, the steps comprising the cleaning, polishing, coloring and packing of the fruit in citrus packinghouses must be "manufacturing", and the Congress has found the application of color to be an "economic necessity" to the citrus industry.

Therefore, whether the coloring of oranges is deemed to be a "production" practice or a "manufacturing practice" it is comprehended by the language of the act, which mandatorily requires that "the Secretary **shall**" fix tolerances when necessary for the protection of the public health, i.e., when a color that is harmless as used might be toxic when **used in larger quantities.**

We respectfully submit that, whether the coloring of oranges is a production or manufacturing practice, within the meaning of Section 402 (a), F&DA's contention was decided by the Congress, after a full hearing, when considering H.R. 7732, which became P.L. 672. The House Committee on Interstate and Foreign Commerce (p-2, H.R. Report No. 1982; 84th Congress, 2d Session) found as follows (under "Purpose Of The Bill"):

> "The purpose of the bill, as amended, is to permit the orange industry to continue for a maximum period of 3 years (until March 1, 1959) the long-established practice of artificially coloring with a coal-tar color designated as FD&C Red 32 oranges which are ripe but whose skins do not have the characteristic orange color. The standards of maturity which such oranges must meet are established by the law of the States in which the oranges are grown."
>
> **"This practice has become an economic necessity for a major segment of the orange industry,** since large quantities of oranges grown in Florida and Texas would meet with strong consumer resistance if they were not articially colored."

The Senate Committee on Labor and Welfare (Senate Report 2391, 84th Congress, 2d. Session) used the same identical language at page 1 of that report.

In both Houses the Bill thus reported went on the consent calendar and was passed unanimously, thereby formally approving those reports. We respectfully sub-

mit that this Congressional finding is dispositive of F&DA's stated contention.

In view of the Secretary's "conclusions" 2 in the Final Order (R. 282) and hearing in mind the Secretary's contentions that the word "harmless" must be construed in its absolute sense, and that the Act does not authorize tolerances, it is pertinent to consider:

(1) If the statute does not authorize tolerances, and if there be no relationship between Sections 406 (a) and 406 (b) of the Act, by what authority were tolerances prescribed for poisons and deleterious substances in coal tar colors under Sections 135.02 and 135.03 of Coal Tar Colors Regulations?

(2) If there is no relationship between Sections 406 (a) and 406 (b) of the Act, why do those tolerance regulations for colors certified under Section 406 (b), use the language of Sec. 406 (a) of the Act?

3. Upon what supposed rule of construction does the Secretary rely to support his insistance upon his view that although Sec. 402 (c) requires certification of coal tar colors under "Section 406", in its entirety, such requirement applies to Sec. 406 (b) only and does not in anywise refer to Section 406 (a)?

(4) Whether the Circuit Court, Fifth Circuit, erred in holding that the Secretary had authority under the Federal Food, Drug and Cosmetic Act to limit the use of Red 32 to use in coloring oranges.

This point was not raised in the Second Circuit Court, but was raised by the color manufactures (JA 47) and by this Respondent (R. 237) in the Departmental proceedings and was raised by this Respondent in the Fifth Circuit Court, contesting the statement made by the Secretary (last sentence, Finding of Fact 10, R. 282) which reads:

"Nor is there authority to limit a color, once certified, to a single food — for example, FD&C Red No. 32 for use in color-added oranges."

We respectfully invite the attention of the Court to the following excerpts from F&DA Coal Tar Color Regulations, still in effect:

At. p. 3: Under **"Straight Colors — Food, Drugs and Cosmetics"**

"Section 135.03. List of straight colors, and specifications for their certification for use in foods, drugs and cosmetics:

"(a) A batch of straight color listed herein may be certified, in accordance with the provisions of these regulations, for use in food **(subject to the restrictions prescribed by subsection (c) hereof)** drugs and cosmetics, if such batch conforms to the requirements of section 135.02 and to the specifications herein set forth for such color." (Emphasis supplied).

Then on p. 8, still under Section 135.03, we find "lakes" defined as being:

"Any lake made by extending on a subtratum of alumina, a salt prepared from one of the water soluble straight colors hereinbefore listed in this subsection by combining such color with the basic radicle aluminum or calcium".

Immediately thereafter (p. 8) we find "specifications" for "lakes" and subsection (b) designating any "lake" thus made as being a straight color and stating how each "lake" shall be named.

Then (p. 9) there appears, as subsection (c) of Section 135.03, the restriction mentioned in subsection (a) above quoted:

"c" No lake listed in subsection (a) shall be certified for any use in food **except external appli-**

cation to shell eggs." (Emphasis supplied)

At p. 35-36, under: "Sections 135.06. Mixtures which may be certified", we find:

> "(d) No mixture which contains a lake listed in section 135.03 shall be certified for any use in food except external application to shell eggs."

At. pp. 38-39: "Section 135.09 Certification."

Provides for and authorizes certification "subject to the terms, and conditions and restrictions prescribed by section 135.10"

At. pp. 39-40: "Section 135.10. Limitations of Certificates":

> "(i) If a coal tar color from a batch containing any lake listed in section 135.03 is used in coloring any food except shell eggs, such color so used shall be considered to be from a batch that has not been certified in accordance with these regulations."

At. p. 40-41, under: "Section 135.11. Labeling":

Provides that label for such lakes or diluents thereof shall bear the statement: "Not for use in coloring any food except shell eggs."

Other restrictions on or requirements as to "lakes" formulated pursuant to section 135.03, will be found under "Section 135.08, Requests for certification", in subsection 5, at p. 38; in "Sample Forms" at pp. 49, 50, 51, 52, and in "General labeling requirements for coal-tar colors" at p. 53.

Thus, to provide all needed colors for Easter eggs, F&DA's Coal Tar Color Regulation 135.03, at p. 8, carries a definition of a "lake" that permits the manufacture of "lakes" from any or all of ten water suluble FD&C Colors listed, then provides (Sec. 135 03 (c) p. 9) that no such lake "shall be certified for any use in food except external application to shell egg." Thus F&DA undertakes to do the laboratory work incident to

the certification of ten coal-tar colors **which must not be used for any purpose save to color Easter eggs.** — and to police such use.

In order to so accommodate the coloring of Easter eggs, F&DA's Coal-Tar Color Regulations carry, all told, sixteen items comprising specific regulations, or exceptions to regulations, or restrictions as to regulations.

We respectfully direct the attention of this Court to the fact that F&DA has gone to these e xt r e m e lengths in order to make available for coloring Easter eggs a supply of colors that, quite obviously, are completely unsafe for use in foods.

Moreover, they have done this notwithstanding a fact concerning which any school child who ever colored his own Easter eggs could have informed them — that when the eggs are dropped in the hot, sometimes boiling, dye solution, it is common for one or more of the eggs to crack, when the dye enters and colors the entire white of the egg, which is then eaten.

Moreover, certain of those regulations disclose that it was then contemplated that other food colors might be certified subject to a restriction limiting t h e use thereof to a specific food.

Thus, Section 135.06, subsection (a) (3) at p. 35 provides that a mixture of FD&C colors may be certified, **if**

> "no diluent (***) in such mixture is a non nutritive substance, unless such mixture is for external application to shell eggs, **or for use in coloring a food specified in the request for certification of such batch**."

Then, at Section 135.11, subsection (a) (4), provision is made for a labeling to read: **"Not for use in coloring any food except————"**. This labeling was not intended to be used on colors for Easter Eggs. It provides for labeling some other color, also restricted to use on some

specific food, because, five lines further on, another labeling is called for, to read: "Not for use in coloring any food except shell eggs."

So, all of the colors needed for coloring Easter eggs are certified, although such colors are obviously unsafe for use in foods. Such certification continues, while F&DA insisted before two Circuit Courts and before this Court that, to be certifiable, every coal tar food color must be "harmless" in the absolute sense of the word.

As before stated, this question was not raised or considered in the Second Circuit. This Respondent raised it in his Department pleadings (R. 237) and in the Fifth Circuit case, where that Court held:

> "In the order of the Secretary it is stated that there is no 'authority to limit a color, once certified, to a single food — for example, FD&C Red No. 32 for use in color-added oranges'. * * * In the Food and Drug Administration Regulations promulgated in 1955, a number of coal-tar colors were listed for certification for use in food, drugs and cosmetics. Among those are colors designated as 'lakes'. The regulations provide that 'No lake listed in paragraph (a) of this section shall be certified for any use in food except external application to shell eggs.' We shall not indulge in speculation upon the comparative porosity of egg shell and orange peel. We merely observe that the Secretary restricted the use of a group of coal-tar colors to a single food, and we think he was fully empowered to do so." (Petition, pp.43-44)

The Court is now respectfully referred to the statement of the Chairman of the Certified Color Industry Committee (JA 47) offering, on behalf of that entire industry, to restrict the sale of that color for use in coloring oranges, only, and to this Respondent's request that

the Secretary order that this be done (R. 237) to which the Secretary replied with his "Finding of Fact 10" (R. 282):

> "Nor is there authority to limit a color, once certified, to a single food — for example FD&C Red No. 32 for use in color added oranges."

We respectfully submit that the citrus industry of the United States, to which, as formally found by the Congress, the Color Added process is an "economic necessity", is at least as important as the Easter egg industry, and that the flat refusal of the Secretary to accord to the colors needed for coloring oranges an equality of treatment with Easter Eggs colors, constituted an arbitrary, capricious and discriminatory use of the powers of his office.

Conclusion

We respectfully submit that by the foregoing we have conclusively shown that:

(a) While F&DA have contended in two Circuit Courts, and now contends in this Court, that the word "harmless" must be construed in its absolute sense (as to which both Circuit Courts disagree with F&DA) yet F&DA has from the beginning construed, and continues to construe the word in a relative sense, by certifying coal tar colors which contain small amounts of known deadly poisons, of known cumulative properties, to-wit: arsenic, lead and other poisonous heavy metals, which cannot possibly be "harmless" in the absolute sense of the word, nor could a color containing them be legally certified, unless that word be construed as "harmless in the amounts used."

(b) While F&DA have contended in two Circuit Courts, and now contend in this Court that there is no provision in the statute authorizing tolerances for coal tar colors, and that there is no relationship between sec-

tions 406 (a) and 406 (b) of the Act, yet in Section 135.02, at p. 3 of F&DA Coal Tar Color Regulations, they publish tolerances for poisonous arsenic, lead and heavy metals in all certified coal-tar colors, and, in Section 135.03, publish tolerances for other and various deleterious substances in each of the 15 colors still certified for use in foods, drugs and cosmetics.

We respectfully submit that the language used in Section 135.02 (the last clause whereof is lifted verbatim from Section 406 (a) of the Act, and section 135.03, conclusively proves that the Secretary has had, and since 1940 has exercised, and today still exercises, the power to fix tolerances for poisons and deleterious substances in coal-tar colors. Since 406 (a) is applicable to colors certified under 406 (b) for that purpose, certainly it is applicable for all pertinent purposes, i.e., fixing maximum amounts (tolerances) for use of the colors in foods.

(c) While F&DA contended in the Fifth Circuit (but not in the Second Circuit and not, so far, in this Court) that the Act does not permit the limiting of a color once certified to a particular use "for example, FD&C Red No. 32 for use in color-added oranges", yet, since 1940 the Secretary **has had and has exercised and today is still exercising, the power to limit the use of a particular certified color to the coloring of one specific food;** that not only has the Secretary so limited such use, but has gone infinitely further, by setting up specific provisions permitting certification of coal-tar colors (lakes) which are, quite obviously, wholly unsafe for use in foods generally, in order to insure a supply of certified colors for coloring Easter Eggs, **while insisting that the Act does not permit such limitation as to, "for example, FD&C Red No. 32 for use in Color Added oranges".**

We further respectfully submit that, as to the three questions decided by the Fifth Circuit Court there is no basic conflict between the decision of that Court and

the decision of the Second Circuit Court, because:

As to Question 2: Both Courts, while differing in their approach thereto, definitely held that the word "harmless" must be construed pursuant to the rule laid down by this Court in **U.S. vs. Lexington Mill & Elevator Co.** (232 U.S. 399), hence there can be no basic conflict between the decisions of those Courts on that Question.

As to Question 3: As shown (p. 42 supra) the Second Circuit elected not to pass upon the general authority of the Secretary to fix tolerances for coal-tar colors under the provisions of Subsection 406 (a), but confined itself to a finding that "under the circumstances disclosed in the record" Appellants could not require the Secretary to do so in that case. There cannot, therefore, be any basic conflict between that part of the decision of the Second Circuit Court and the decision of the Fifth Circuit Court, with a complete record before the Court, that the Secretary is required to establish tolerances for coal-tar colors.

As to Question 4: The matter of the power of the Secretary to limit the use of a particular color to the coloring of a single specific food, was not presented to or decided by the Second Circuit Court, hence there is no basic conflict on that Question.

There is no suggestion by the Secretary that the decision of the Fifth Circuit Court is in anywise in conflict with any decision of the Supreme Court, nor does any such conflict exist.

We, therefore, respectfully submit that, for

all of these reasons, the petition for certiorari should be denied.

Respectfully submitted,

Morris E. White
of Counsel for Respondent
Frank R. Schell

J. Lewis Hall,
Tallahassee, Florida
Of Counsel.

CERTIFICATE OF SERVICE

I hereby certify that on this first day of March, A.D. 1958, I have served two copies of the foregoing brief on each of the following persons, by air mail, postage prepaid:

Honorable Marion B. Folsom, Secretary,
Department of Health, Education and Welfare,
Washington, D. C.

Honorable J. Lee Rankin,
The Solicitor General,
Washington, D. C.

Honorable Rufus D. McLean,
Acting Assistant Attorney General,
Washington, D. C.

Honorable Beatrice Rosenberg, Attorney,
Department of Justice,
Washington, D. C.

Honorable William W. Goodrich,
Assistant General Counsel,
Department of Health, Education and Welfare,
Washington, D. C.

Honorable J. Hardin Peterson,
208 South Tennessee Avenue,
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Morris E. White
Of Counsel For Respondent
Frank R. Schell.

Tampa, Florida
March 1st, 1958.

UNITED STATES COURT OF APPEALS

For the Second Circuit

———:———

No. 361—October Term, 1955

(Argued May 14, 1956 Decided August 10, 1956.)

Docket No. 23983

———:———

The Certified Color Industry Committee, Allied Chemical & Dye Corporation, American Cyanamid Company, Bates Chemical Co., Inc., Dyestuffs and Chemicals, Inc., H. Kohnstamm & Co., Inc., Wm. J. Stange Co., Sterwin Chemical, Inc. and Warner-Jenkinson Mfg. Co.,

Petitioners,

—against—

The Secretary of Health, Education and Welfare, Marion B. Folsom,

Respondent.

———:———

Before:

Medina and Waterman, *Circuit Judges,*
and Murphy, *District Judge.*

———:———

Petitions to review an order of the Secretary of Health, Education and Welfare, made pursuant to 21 U. S. C. A. Sections 346(b), 354, 364 and 371, delisting three coal-tar colors manufactured by petitioners. Order affirmed.

———:———

Cravath, Swaine & Moore, New York City (Albert R. Connelly, and Michael F. Markel, of counsel), *for petitioners.*

Warren Olney III, Asst. Attorney General, John T. Grigsby and Frank J. Kierman, Attorneys, Dept. of Justice (Paul M. Steffy, and William W. Goodrich, of counsel), *for respondent.*

MURPHY, *District Judge:*

These are petitions to review an order of the Secretary of Health, Education and Welfare delisting certain coal-tar colors (FD & C Orange No. 1, Orange No. 2 and Red No. 32) manufactured by petitioners. Prior to this order the dyes in question had been certified since 1939 as "harmless" and placed on the approved list for unrestricted use in foods, drugs and cosmetics. Prompted by hearings before a Select Committee of Congress to Investigate the Use of Chemicals in Foods concerning the toxicity and possible carcinogenicity of coal-tar colors, respondent conducted extensive experimental research with laboratory animals which conclusively showed that the colors in question produced substantial deleterious effects and sometimes death. This information and experimental data was given to petitioners sufficiently in advance of the hearing to permit them to offer contradictory evidence. After the hearing on notice, at which petitioners offered no opposing scientific data, the Secretary found the dyes to be "not harmless and suitable for use in coloring food or for use in coloring drugs or cosmetics intended for other than external application," and ordered that they be deleted from the listing.

This order was made November 10, 1955, effective February 10, 1956. Petitioners filed the instant Petition to Review on February 7, 1956, three days before their time would have expired. On January 27, 1956, only twelve days before, they made a motion before the Secretary to reopen the hearings to receive evidence of the maximum extent to which these colors are used in foods (but not of drugs or cosmetics) under normal conditions of use, which were represented to be far less than the levels of administration causing damage to the test animals. This motion was denied on February 20, 1956, on a number of grounds, viz., (1) as to the color Red 32 (a) because no safe levels were found for animals and (b) this color recently caused 196 persons (adults and children) to become acutely ill after eating popcorn with this color added; (2) man appears to be much more susceptible to color dyes than test animals; (3) the proposed proof was inaccurate and incomplete and did not take into account all uses; (4) the statute did not permit tolerances for toxic colors; (5) although the tests proved the colors toxic they did not establish the extent of toxicity to a certainty so as to permit the establishment of safe tolerance, and (6) the Secretary had no authority to establish tolerances with regard to colors.

Petitioners suggest that the basic question for review is whether the statutory language "harmless and suitable for use" (Federal Food, Drug and Cosmetic Act, Section 406(b), 21 U. S. C. 346(b) is to be interpreted in a absolute sense or in a relative sense meaning "incapable

of producing harm under normal conditions of use." Subsidiary to this, they say, is the question whether the Secretary is authorized to impose limitations or tolerances under which colors may continue to be certified. It is their position that the legislative intent can be found in the prior construction by respondent's predecessors which Congress was aware of since it knew that coal-tar colors were toxic and must have realized that their authorized use would have to have some relation to the quantities used. All of this follows, it is argued, since many substances, e.g., salt and vinegar, are concededly not harmless in an absolute sense. The second string to their bow is the argument that the Secretary should authorize limitations or tolerances for these colors for normal use the same as the Secretary does with regard to poisonous or deleterious substances added to food but which are necessary or unavoidable in good manufacturing practice. (Federal Food, Drug, and Cosmetic Act, Section 406 (a), 21 U. S. C. 346(a).)

We turn to the legislative history of the act in an effort to resolve the question whether "harmless" should be construed in a relative or absolute sense. The 1906 Act provided that food should be deemed adulterated "if it contain(s) any added poisonous or other added deleterious ingredient which may render such article injurious to health." (Food and Drugs Act of 1906, Section 7, 34 Stat. 769.) Although no specific provisions were then enacted dealing with coal-tar colors, the Food and Drug Administration early recognized the necessity of special treament for these dyes. Without express statutory authority it issued regulations to the effect that only harmless colors might be used and proceeded to certify for use only those coal-tar dyes which satisfied its specifications. This practice continued until the act was amended in 1938. Under the amended statutory scheme a food is deemed adulterated, "If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health * * *" (Federal Food, Drug, and Cosmetic Act, Section 402(a), 21 U. S. C. 342(a)). Section 402(c) (21 U. S. C. 342 (c)) was added to deal specifically with the problem of coal-tar colors. It provides flatly that a food shall be deemed adulterated if it contains a coal-tar color other than one from a batch certified under Section 406(b), (21 U. S. C. 346(b). This latter section authorizes the Secretary to "promulgate regulations for the listing of coal-tar colors which are harmless and suitable for use in food, and for the certification of batches of such colors * * *." Section 406(a), (21 U. S. C. 346(a) gives the Secretary permission to set up tolerances for added poisonous or deleterious substances which are required or cannot be avoided by good

manufacturing practice. At least to the extent that the amendment authorized the certification of coal-tar colors, it codified the administrative practice of the past 30 years.[1]

Petitioners argue that the 1938 amendment, insofar as these sections are concerned, amounts to nothing more than legislative recognition of existing practice and procedure; that the word "harmless" must be equated to "added poisonous or other added deleterious ingredient which may render such article injurious to health," and that these words must be given the meaning assigned to them in *Wood Mfg. Co. v. United States*, 286 Fed. 84 (7th Cir. 1923). The *Wood* case adopted a standard of relativity and held that an infinitesimal quantity of arsenic in a coal-tar color was not a poisonous or deleterious substance, injurious to health, as ordinarily used, and that the government was required to prove that the substance was in fact injurious as used. Respondent, on the other hand, urges that the use of a different word—"harmless"—instead of the more familiar statutory language is evidence of Congressional intent to provide an absolute standard. We are unable to agree with either of these interpretations.

However, we do agree that the word "harmless" as used in Section 406(b) must have some relation back to Section 402(a). But the provisions of that section, as amended, are substantially different from those of its predecessor—Section 7 of the 1906 Act. The new provision treats deleterious substances separately depending upon whether they are added to or are an integral part of the food. Thus, if the deleterious substance is inherent in the food there nevertheless is no adulteration if the quantity of the substance used does not *ordinarily* render it injurious to health. But if the complained of ingredient is an added one, then the food is adulterated if the substance *may* render it injurious to health. This, so far as added substances are concerned, would seem to indicate legislative discontent with the *Wood* case, and a return to the principles,

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1. Parenthetically it may be noted that on July 9, 1956, the President signed into law a bill further amending Section 402 by the addition of a provision permitting the use of Red 32 on the skins of oranges not intended for processing, such permission to last only until March 1, 1959 or until another suitable color is listed under Section 406, whichever is sooner. Pub. L. No. 672, 34th Cong., 2nd Sess., Chapter 530 (July 9, 1956). What is significant, however, is the vast difference between the bill as proposed and the bill as passed. The former providd for the promulgation of regulations respecting the listing of coal-tar colors for use on orange skins "which are safe in the manner in which used and suitable for such use." The Secretary objected to this but did not oppose the bill in its *final* form. Hearings Before the Subcommittee on Health and Science of the House Committee on Interstate and Foreign Commerce, 84th Cong., 2nd Sess. at 1-3 (1956).

enunciated by the Supreme Court in *United States* v. *Lexington Mill & Elevator Company*, 232 U. S. 399 (1914), wherein it was said:

> "It is not required that the article of food containing added poisonous or other added deleterious ingredients must affect the public health, and it is not incumbent upon the Government in order to make out a case to establish that fact. The act has placed upon the Government the burden of establishing * * * that the added poisonous or deleterious substances must be such as may render such article injurious to health. The word 'may' is here used in its ordinary and usual signification, there being nothing to show the intention of Congress to affix to it any other meaning. It is, says Webster, 'an auxiliary verb, qualifying the meaning of another verb by expressing ability * * * contingency or liability, or possibility or probability.' In thus describing the offense Congress doubtless took into consideration that flour may be used in many ways, in bread, cake, gravy, broth, etc. It may be consumed, when prepared as a food, by the strong and the weak, the young and the old, the well and the sick; and it is intended that if any flour, because of any added poisonous or deleterious ingredient, may possibly injure the health of any of these, it shall come within the ban of the statute. If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act" (at p. 411).

By restricting the ordinary usage test to non-added substances, the inference is inescapable that Congress meant to similarly restrict the *Wood* case and to correspondingly restore the doctrine of the *Lexington Mill* case. Definition of "harmless" along these lines can scarcely be considered too strict in view of the stringent provisions relating to coal-tar colors. Section 402 (c) deems food adulterated if it contains such a dye, regardless of whether it could possibly cause any harm, if it does not come from a certified batch.

Thus, the government need not prove that the use of Orange 1 and 2, and Red 32, is in fact injurious to health. It is enough if it shows that such addition "might render the article of food injurious." *United States* v. *Lexington Mill & Elevator Company*, supra, at page 410. This it has done by the overwhelming weight of the evidence. Without analyzing the scientific data in the record, suffice it to say that the uncontradicted testimony shows that the least toxic of the three colors in question had serious immediate effect on human beings and that the overall effect on the laboratory animals by proof on autopsy was alarm-

ing. Consequently, the delisted colors are not "harmless" within the meaning of Section 406(b).

The subsidiary question raised by the denial of a rehearing, relating to the Secretary's authority to impose tolerances under which the colors may continue to be used need not be answered. All we need decide is whether or not petitioners can require him to establish such tolerances. Under the circumstances disclosed in the record we hold that they have no right to do so. There are two reasons for this. In the first place there is nothing in the record to indicate how much of these coal-tar colors a human being could ingest over a period of years without any harmful effects, nor did petitioners propose to introduce any. The respondent's conclusion in this connection is as follows:

> "While a safe level of administration to test animals is disclosed by the record in the case of FD & C Orange No. 1, the record also discloses that the color has adverse effects upon man at a level well below the safe level of administration to test animals. The safe level of administration of FD & C Orange No. 2 to test animal is well below the level at which FD & C Orange No. 1 was found safe to test animals. It is therefore, even more toxic than FD & C Orange No. 1. No safe level of administration was found even in test animals for FD & C Red No. 32."

Furthermore, it may be impossible to demonstrate the precise cumulative effect over 20 or 30 years of consumption of specified amounts of color and therefore impossible to prescribe safe tolerances. We think that the Secretary's findings that such tolerances cannot be determined should be accepted, and that they are dispositive of the case. The colors here involved have been shown to be alarmingly toxic. To be sure, it is not certain that continued consumption at present rates will be harmful to a normal consumer. But it is sufficiently likely to make the Secretary's decision a completely reasonable one. Failure on his part to provide an adequate margin of safety might well constitute an abuse of discretion. Cf. *Atlas Powder Co.* v. *Ewing*, 201 F. 2d 347, 355 (3rd Cir. 1952) cert. den. 345 U. S. 923 (1953). The tests were conducted for the sole purpose of determining whether or not the colors were harmless. Now that their toxicity has been amply demonstrated it would be unconscionable for any court to require the Secretary to permit their use without the clearest and most uncompromising evidence that usage at certain levels was absolutely safe. It must be remembered that while petitioners did nothing to obstruct the accumulation of data on this point they certainly did nothing to advance the cause of science. The industry made no pharmacological investigation of its own after 1938, submitted no evidence and readily accepted the results of the studies made by the Food and Drug Administration.

But quite aside from this lack of any evidence in the record indicating a safe level of consumption, there is, as a practical matter, a far more serious objection to requiring a schedule of tolerances. Relying on Exhibit A to the petition to reopen the hearings it appears that the colors in question are used in cakes, cookies, pies, bread, cheese, ice cream, frankfurters, bologna, spreads, oranges, canned and frozen vegetables, candy, desserts and puddings, soft drinks, condiments, soups, pickles, olives and prepared dishes, as well as in unenumerated drugs and cosmetics. Assuming for the moment that the Secretary could determine that X milligrams of coal-tar color per day could be taken for 25 years with absolute safety—How, considering the vast number of items which contain the dyes and the extremely diverse consumer habits of the American public, could he possibley guard against the ingestion of more than X milligrams per day? The short answer, of course, is that he could not. He has made the following specific finding:

> "There was no evidence on which findings could be made concerning how much of the three colors is likely to be ingested by man from his food, drugs and cosmetics. Some interested persons, taking their own products, attempted to show that the amounts ingested would be small to be the point of insignificance. But those contentions leave aside the occurence of the colors in the products of others, as well as the fact that upon certification of a color the Deparment has no means of controlling the amounts of colors used in a variety of food, drugs, and cosmetics. Nor is there authority to limit a color, once certified, to a single food—for example, FD & C Red No. 32 for use in color-added oranges."

Thus the problem is far different from the one presented recently to Congress when the act was amended to permit the use of Red 32 on orange skins not intended for processing. With only one product contaminated it was not too difficult to argue that such small amounts were involved that a man would have to drink 5000 gallons of orange juice a day before experiencing any adverse effects. Hearings Before the Subcommittee on Health and Science of the House Committee on Interstate and Foreign Commerce, 84th Cong., 2d Sess. at 13 (1956).

In view of the impossibility of controlling the intake of coal-tar colors, even assuming maximum tolerances per item could be established, the Secretary acted within his discretion in refusing to reopen the hearings. Cf. *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U. S. 218 (1943).

Order affirmed.

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CHRONIC TOXICITY STUDIES ON FOOD COLOURS

PART II. OBSERVATIONS ON THE TOXICITY OF FD&C GREEN NO. 2 (LIGHT GREEN SF YELLOWISH), FD&C ORANGE NO. 2 (ORANGE SS) AND FD&C RED NO. 32 (OIL RED XO) IN RATS

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THIS paper describes further studies on the chronic toxicity of food colours. In Part I of this series some chronic effects of Oil Yellow AB and OB in rats were reported[1]. It has previously been reported by other workers that some colours belonging to the azo and triphenylmethane classes caused tumours to develop in animals after subcutaneous injections[2,3]. As some of these colours are being used in food it was thought worthwhile to examine them for chronic oral effects in rats. The effects of the oral administration of FD&C Green No. 2, FD&C Orange No. 2 and FD&C Red No. 32 on growth, food consumption, food efficiency, blood hæmoglobin, and on the pathology of a number of organs are presented in this paper.

METHODS

The methods employed were similar to those reported for the two yellow colours[1]. The food colours were incorporated in the laboratory diet in the following concentrations: FD&C Green No. 2, 0·03, 1·5 and 3·0 per cent; FD&C Orange No. 2 and FD&C Red No. 32, 0·03, 0·75 and 1·5 per cent. The rats were approximately five to six weeks of age at the start of the experiment. The animals were kept in groups of two to a cage and were given free access to their respective diets and water. Their body weight and food consumption were recorded weekly. For more accurate evaluation of food consumption it would have been preferable to place only one rat in a cage, but this was not possible. Post-mortem examinations were made where possible on rats which died on test. All surviving rats were killed at the end of the experiments and post-mortem examinations were made. Many of the organs were weighed and prepared for histological examination. As a result of an unfortunate accident at the end of the fourth week to the male rats on a dietary concentration of 1·5 per cent. FD&C Green No. 2, data on these rats are not included.

RESULTS AND DISCUSSION

The Effect on Growth Rate, Food Consumption and Food Efficiency

Growth, food consumption and food efficiency curves for the groups receiving the various dietary concentrations of the three colours are shown in Figures 1 and 2. Growth rate, food consumption and food

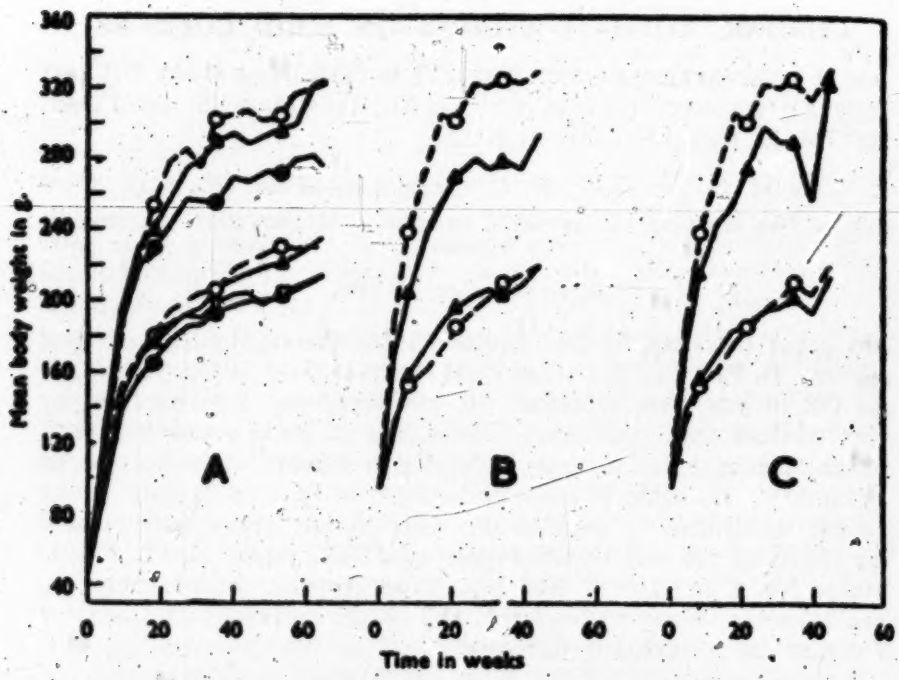

FIG. 1. Growth rate curves for control rats and those receiving the colours. Lower curves are for female rats and upper curves for male rats.

A. FD&C Green No. 2: B. FD&C Orange No. 2: FD&C Red No. 32

○ control; ▲ 0·03 per cent.; ▽ 1·5 per cent.; ● 3·0 per cent.

efficiency were not significantly affected by any of the three colours at the 0·03 per cent dietary level. However, for FD&C Red No. 32 and FD&C Orange No. 2 at the higher concentrations of 0·75 and 1·5 per cent. of the diet, growth rate, food consumption and food efficiency were noticeably affected and all rats in these two groups died before completion of the experiment. For FD&C Green No. 2, two dietary levels, 0·03 and 1·5 per cent. had no effect on growth rate, food consumption or food efficiency, but the 3·0 per cent. level noticeably affected growth rate. This may have been partly due to the amount of food consumed, which was somewhat reduced on this dietary amount. Daily doses of 200 mg./kg. and 400 mg./kg. of FD&C Red No. 32 and FD&C Orange No. 2 for 20 weeks to rats affected growth, food consumption and food efficiency, as shown in Tables I and IV.

The Effect of Mortality

At the end of the test period (65 weeks) the mortality of rats on FD&C Green No. 2 ranged from 52 to 68 per cent. for the respective groups, as shown in Table II. The control group mortality was 68 per cent. The mortality for the respective groups on dietary concentrations of FD&C Green No. 2 was not significantly different from the control. For the other two colours there was 100 per cent. mortality at the 0·75 and

TABLE I

SUMMARY OF DATA ON MORTALITY, FOOD CONSUMPTION AND FOOD EFFICIENCY WHEN FOOD COLOURS WERE GIVEN BY STOMACH TUBE FOR 20 WEEKS

Dose	Sex	No. rats on test	Mortality	Food consumption g./rat/day	Food efficiency g. gain/g. food consumed × 100
Control	M	10	0	13·2	5·2
	F	10	0	11·1	4·7
200 mg./kg./orally/daily FD&C Red No. 2	M	10	6	12·5	2·9
	F	10	0	12·7	3·1
200 mg./kg./orally/daily FD&C Orange No. 2	M	10	6	13·9	3·3
	F	10	2	10·3	4·5
400 mg./kg./orally/daily FD&C Red No. 32	M	10	5	12·1	1·7
	F	10	3	10·1	1·8
400 mg./kg./orally/daily FD&C Orange No. 2	M	10	6	10·3	1·9
	F	10	6	10·0	0·6

1·5 per cent. levels by the time the experiment was ended as shown in Table III. By the end of 20 weeks all the rats on the 1·5 per cent. level of FD&C Red No. 32 had died, and at the end of 40 weeks all the rats on the 0·75 per cent. level had died. It was not possible to make autopsies on all the animals which died during the experiment, but the tissues and organs of many of those dying on the 0·75 and 1·5 per cent. dosage were stained with the colours. The kidneys were soft, dark and swollen. The spleen was enlarged and dark in colour. The picture was one of acute toxæmia.

TABLE II

CUMULATIVE NUMBER OF DEATHS

Concentration of colour in diet %	Sex	No. Rats on test	Time in weeks on test														
			1	3	5	10	15	20	25	30	35	40	45	50	55	60	65
FD&C Green No. 2																	
Control	M	25	1	6	7	8	10	11	12	13	14	14	14	14	14	16	17
	F	25	0	1	1	2	3	3	3	6	6	7	8	8	8	8	10
0·03 per cent.	M	25	0	0	0	1	1	2	4	8	8	8	8	9	11	13	14
	F	25	0	0	0	0	1	4	4	5	6	7	9	11	12	13	13
1·5 per cent.	F	25	0	0	0	0	1	1	2	2	2	3	5	7	13	13	14
3·0 per cent.	M	25	0	0	2	3	3	3	3	4	10	10	11	11	12	13	16
	F	25	0	0	0	2	2	3	4	6	8	8	9	10	10	14	14

The Effect on Organ Weights

Organs of surviving rats were weighed at the termination of the test. The mean weights (in mg./g. of body weight) are shown in Table IV. The mean weights of a number of organs deviated significantly from those of corresponding controls. Heart, liver, spleen, kidneys and testes were the organs chiefly affected. In very few instances where increases or decreases in organ weights occurred was it possible to demonstrate pathological changes; the changes demonstrated in the testes are an exception. In a number of cases the organ weights were about the

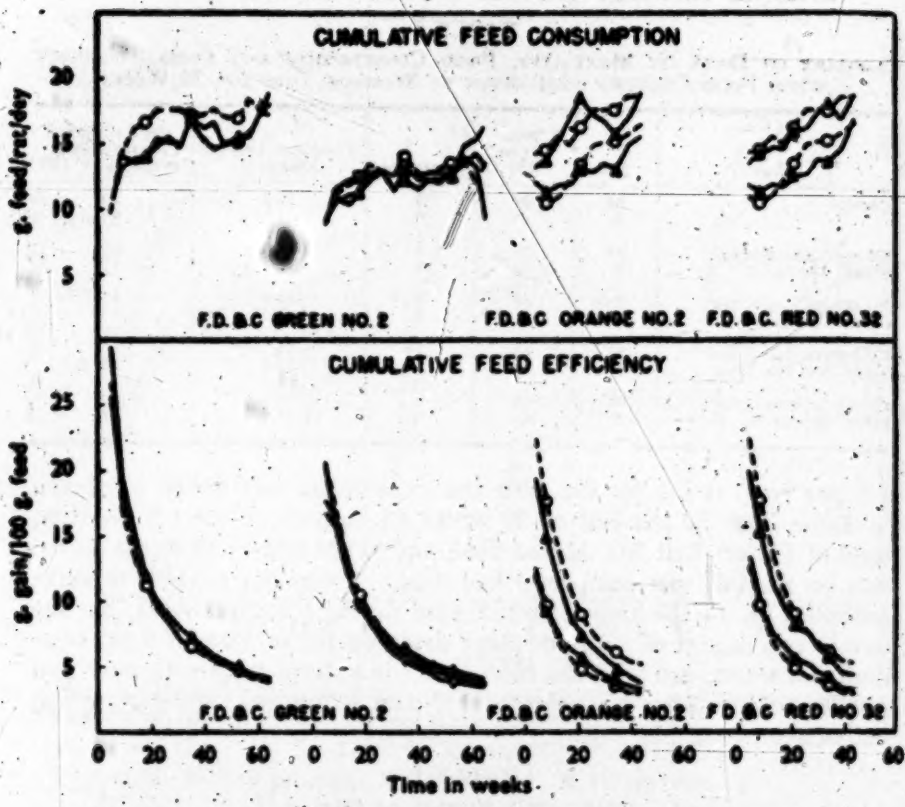

FIG. 2. Food consumption and food efficiency curves for control and test rats, male and female. For FD&C Green No. 2, values for males are shown on the left. For the other two colours, the upper curves represent male rats and the lower curves female rats.

○ Control; ▲ 0·03 per cent., ▽ 1·5 per cent., ● 3·0 per cent.

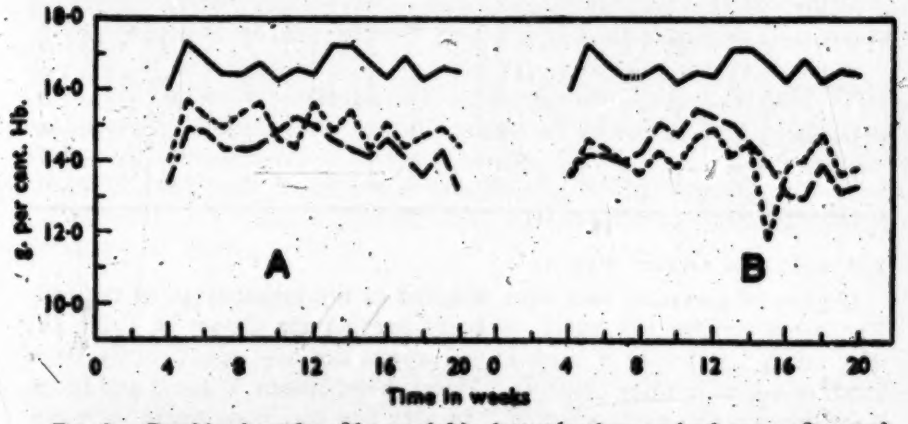

FIG. 3. Combined results of haemoglobin determinations on both sexes of control rats and those given the two colours at different doses. A. F.D.&C. Red No. 32. B. F.D.&C. Orange No. 2.

— Control: - - - 200 mg./kg./rat, oral: — — 400 mg./kg./rat oral.

same as the controls but the body weights of the test animals were less than the controls, suggesting the possible utilization of muscle protein. In other cases the body weights of test and control animals were about the same but the organ weights differed significantly. The changes observed in the organs in these cases appeared like compensatory changes. These results do not demonstrate a correlation of organ weight and the histopathological changes except with the testes.

TABLE III

CUMULATIVE NUMBER OF DEATHS

Concentration of colour in diet	Sex	No. Rats on test	Time in weeks on test											
			2	4	8	12	16	20	24	28	32	36	40	44
FD&C Red No. 32														
Control	M	20	0	2	3	4	5	7	10	11	11	12	13	13
	F	20	0	0	2	2	3	6	7	7	7	7	7	7
0·5 per cent.	M	20	0	0	2	3	3	7	9	9	9	9	16	18
	F	20	0	0	1	1	5	5	6	6	6	6	8	9
0·75 per cent.	M	20	2	3	4	11	15	15	13	16	17	19	20	
	F	20	0	0	0	9	11	13	15	15	15	16	20	
1·5 per cent.	M	20	2	8	11	17	19	20						
	F	20	0	2	10	18	19	20						
FD&C Orange No. 2														
Control	M	20	0	2	3	4	5	7	10	11	11	12	13	13
	F	20	0	0	2	2	3	6	7	7	7	7	7	7
0·5 per cent.	M	20	0	0	1	2	4	6	6	7	8	9	13	13
	F	20	0	0	0	0	1	2	3	4	5	6	7	7
0·75 per cent.	M	20	2	5	10	17	20							
	F	20	3	6	10	17	19	20						
1·5 per cent.	M	20	3	12	17	20								
	F	20	4	10	16	20								

Hæmatology

Hæmoglobin determinations were made weekly for 20 weeks on groups of male and female rats, 10 rats to a group, given daily oral doses of 200 mg./kg. and 400 mg./kg. respectively of FD&C Red No. 32 and FD&C Orange No. 2. A slight modification of the pyridine-hæmochromogen method of Rimington was used[4]. The combined results of these determinations on both sexes are shown in Figure 3, and the mean values of the final determinations are shown in Table IV. The combined blood hæmoglobin values for both sexes show a significant decline in all groups on both colours. This trend was also evident from an examination of the data obtained on each sex.

Blood hæmoglobin values were also determined on the surviving rats from the other experiments. These values, also shown in Table IV, were about the same as those for the controls.

Histopathology

A detailed examination was made of the hæmatoxylin-eosin stained paraffin sections of a number of organs including lung, heart, liver,

TABLE IV

Comprehensive Summary of Observations on Rats fed FD&C Red No. 32, FD&C Orange No. 2 and FD&C Green No. 2

Product	Dosage	No. weeks on test	No. rats surviving / No. rats on test	Mean body weight g. ± s.e.		Mean Hg (g. per cent.) ± s.e.†	Mean organ weight, mg./g. rat ± s.e.					
				Initial	Final		Heart	Liver	Kidneys	Adrenals	Spleen	Testicles
Males												
Control		44	7/20	97·7±5·1	329·1±26·3	15·8±0·29	3·3±0·08	28·6±1·57	6·4±0·07	0·08±0·007	2·4±0·13	8·8±0·35
FD&C Red No. 32	0·03 per cent. of diet	44	2/20	98·4±6·3	330·0± 6·0	16·1±0·75	3·6±0·05	37·0±4·45	7·0±1·20	0·09±0·007	2·6±0·15	8·9±0·73
FD&C Orange No. 2	0·03 per cent. of diet	44	7/20	94·1±5·8	269·4±24·9	15·3±0·50	3·4±0·03	32·5±3·31	7·2±0·13	0·11±0·013	2·4±0·22	8·4±0·63
Control		20	4/10	118·7±5·7	251·0±11·0	17·3±0·40	3·6±0·05	34·9±1·55	7·6±0·25	0·09±0·005	2·5±0·28	9·7±0·38
FD&C Red No. 32	200 mg./kg./day	20	4/10	113·1±4·8	155·0±18·9*	14·1±0·81*	4·6±0·35*	38·2±0·95	9·5±1·55	0·15±0·038*	2·9±0·60	9·6±1·32
FD&C Red No. 32	400 mg./kg./day	20	5/10	115·7±6·4	160·2±14·0*	12·8±1·50*	4·7±0·38*	53·1±2·96*	9·6±0·71*	0·13±0·016*	4·5±0·46*	9·6±1·65
FD&C Orange No. 2	200 mg./kg./day	20	4/10	115·9±4·0	200·0±18·6*	14·1±0·40*	4·1±0·32	44·4±4·46	8·8±0·73	0·12±0·014	4·5±0·32*	11·0±0·70
FD&C Orange No. 2	400 mg./kg./day	20	4/10	110·7±4·0	152·8±8·6*	13·8±0·64*	5·2±0·18*	44·8±1·59*	8·9±0·49	0·12±0·005	5·0±0·14*	12·9±0·47*
Control		65	8/25	45·6±2·7	323·4±20·0	17·2±0·35	3·2±0·11	30·3±1·01	6·2±0·19	0·08±0·008	2·7±0·26	8·6±0·40
FD&C Orange No. 2	0·03 per cent. of diet	65	11/25	45·5±2·7	323·8±10·9	16·6±0·19	3·4±0·07	32·6±0·82	6·1±0·12	0·08±0·004	2·6±0·11	6·5±0·38
FD&C Green No. 2	3·0 per cent. of diet	65	9/25	45·4±2·7	274·0±12·5*	16·0±0·25*	3·4±0·10	34·9±2·14	6·9±0·38	0·09±0·005	2·3±0·15	5·0±0·69*
Females												
Control		44	12/20	91·7±3·5	219·8± 4·9	15·9±0·22	4·1±0·06	35·7±0·80	7·4±0·21	0·21±0·007	3·4±0·36	
FD&C No. 32	0·03 per cent. of diet	44	11/20	91·8±2·7	214·1± 2·9	14·9±0·66	4·2±0·15	39·2±1·38*	8·1±0·27	0·23±0·010	3·9±0·64	
FD&C Orange No. 2	0·03 per cent. of diet	44	11/20	95·1±3·4	219·4± 5·8	15·6±0·22	4·2±0·13	37·8±1·36	7·8±0·18	0·24±0·011	3·6±0·15	
Control		20	9/10	93·0±3·9	166·9± 6·5	15·7±0·65	4·5±0·41	37·5±1·38	8·2±0·45	0·26±0·031	3·1±0·33	
FD&C Red No. 32	200 mg./kg./day	20	10/10	92·3±4·0	147·6± 5·8*	14·7±0·23	4·5±0·18	43·0±1·73	8·7±0·34	0·20±0·004	4·1±0·15*	
FD&C Red No. 32	400 mg./kg./day	20	7/10	91·6±3·5	124·9± 4·6*	13·4±0·45*	5·0±0·18	51·8±1·92*	9·6±0·14	0·16±0·007*	6·5±2·05	
FD&C Orange No. 2	200 mg./kg./day	20	8/10	88·8±3·3	153·6± 3·1	13·7±0·19*	4·3±0·07	40·2±1·34	7·8±0·30	0·17±0·011	5·6±0·27*	
FD&C Orange No. 2	400 mg./kg./day	20	4/10	89·9±4·0	102·8±11·2*	12·9±1·37*	5·0±0·31	55·1±5·14*	9·9±0·43	0·20±0·022	5·3±0·73*	
Control		65	15/25	39·6±2·4	227·9± 3·9	16·0±0·19	4·1±0·07	35·4±0·84	7·0±0·18	0·22±0·008	3·6±0·13	
FD&C Green No. 2	0·03 per cent. of diet	65	11/25	39·4±2·4	236·7± 6·9	16·4±0·30	3·9±0·09	31·9±1·05*	6·6±0·21	0·21±0·011	3·2±0·06*	
FD&C Green No. 2	1·5 per cent. of diet	65	11/25	39·6±2·3	213·6± 8·7	16·1±0·33	3·6±0·06*	24·4±0·39*	6·1±0·13*	0·16±0·017*	2·7±0·20*	
FD&C Green No. 2	3·0 per cent. of diet	65	11/25	39·7±2·4	210·6± 7·3*	16·0±0·21	4·3±0·12	34·9±1·16	7·3±0·17	0·19±0·005*	3·6±0·22	

* significant at P = 0·05

† determination on 5 rats

TABLE V

SUMMARY OF HISTOPATHOLOGICAL FINDINGS

	Control	Control	FD&C Green No. 2	FD&C Orange No. 2	FD&C Red No. 32	Control	Control	FD&C Green No. 2	FD&C Orange No. 2	FD&C Red No. 32	Control	FD&C Green No. 2	Control	FD&C Green No. 2	Control	FD&C Green No. 2	Control	FD&C Orange No. 2	FD&C Red No. 32	Control	FD&C Orange No. 2	FD&C Red No. 32	Control	FD&C Orange No. 2	FD&C Red No. 32	Control	FD&C Orange No. 2	FD&C Red No. 32
Sex	Male					Female					Female		Male		Female		Male			Female			Male			Female		
Dose	0·03 per cent. in diet					0·03 per cent. in diet					1·5 per cent. in diet		3·0 per cent. in diet		3·0 per cent. in diet		200 mg./kg./day			200 mg./kg./day			400 mg./kg./day			400 mg./kg./day		
Number of rats on test	25	20	25	20	20	25	20	25	20	20	25	25	25	25	25	25	10	10	10	10	10	10	10	10	10	10	10	10
Number of survivors	8	7	11	7	2	15	7	12	13	11	15	11	8	9	15	11	4	4	5	9	8	10	4	4	5	9	4	4
Number of rats examined	5	5	6	7	2	4	7	6	11	10	4	6	5	8	4	6	4	4	4	9	8	10	4	4	5	9	4	4
Duration of test-weeks	65	44	65	44	44	65	44	65	44	44	65	65	65	65	65	65	20	20	20	20	20	20	20	20	20	20	20	20
Bladder parasites			3	4	1	1		2	2	3		2		3		1												
Hydronephrosis						2		1	1	1						2					1							
Chronic glomerulonephritis						1															1							
Pyelonephritis																												
Interstitial nephritis																												
Altered spermatogenesis				1										7														
Necrotic casts in testes tubules																												
Ovary fibroma									1					6														
Ovary cystadenoma																												
Perioophoritis																												
Liver necrosis														1		1												
Lung papilloma																												
Purulent pericarditis																												
Laryngeal abscess							1									1												
Acute tracheitis																												

spleen, thyroid, pancreas, stomach, small intestine, kidney, urinary bladder, adrenal, testes, ovaries and thymus. A summary of the findings is given in Table V. There were no consistent histopathological changes observed in the tissues or organs studied that could be attributed to the toxic effects of the colours with the possible exception of testicular change which was observed in animals on the higher dietary concentrations. These findings were particularly noticeable in rats on dietary levels of 3.0 per cent. FD&C Green No. 2 and in those receiving daily oral dosage of 400 mg./kg. of FD&C Red No. 32. On the 3.0 per cent. level of the green colour testicular change was a constant finding. In seven out of eight animals there was tubular atrophy and incomplete spermatogenesis. The change, although constant, was variable in degree. In some testes a few tubules showed complete absence of spermatogenic cells and in others the spermatogenic cells were greatly reduced. Several tubules in each testis contained deep-blue-staining caseous necrotic casts. Remnants of sperm were present in the necrotic debris. The spermatogenic cells and the supporting network of the tubules were undergoing varying degrees of degenerative changes. In some tubules it was apparent that the necrotic casts were being formed from the degenerating cells.

SUMMARY

1. FD&C Orange No. 2, FD&C Red No. 32 and FD&C Green No. 2 in concentrations of 0.03 per cent. in the diet did not affect growth, food consumption or food efficiency in either male or female rats.

2. In groups receiving FD&C Orange No. 2 and FD&C Red No. 32 in concentrations of 0.75 and 1.5 per cent. in the diet, there was 100 per cent. mortality before the completion of the experiment.

3. FD&C Green No. 2 in a concentration of 3.0 per cent. in the diet adversely affected the growth rate which may have been due in part to the amount of food consumed. At the 1.5 per cent. concentration in the diet of female rats no effect on growth rate, food consumption or food efficiency was observed.

4. Haemoglobin production was not affected by 0.03 per cent. in the diet of either FD&C Orange No. 2 or FD&C Red No. 32, but oral doses of 200 and 400 mg./kg. of these two colours caused a decline in haemoglobin values which was significant in both sexes at 20 weeks. Haeoglobin values were not affected by any of the dosage levels of FD&C Green No. 2.

5. The only significant pathology was found in the testes of those rats receiving a dietary level of 3.0 per cent. of FD&C Green No. 2, or an oral dosage of 400 mg./kg. of FD&C Red No. 32.

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